

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOSH FEIERSTEIN, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

CORREVIO PHARMA CORP., MARK H.N.
CORRIGAN, WILLIAM HUNTER, JUSTIN
A. RENZ, and SHEILA M. GRANT,

Defendants.

Case No.: 1:19-cv-11361-VEC

**AMENDED CLASS ACTION
COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

Lead Plaintiffs Clinton Atkinson, Nabil Saad, and Iuliaa Mironova (“Plaintiffs”), individually and on behalf of all other persons similarly situated, by Plaintiffs’ undersigned attorneys, for Plaintiffs’ complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiffs and Plaintiffs’ own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through Plaintiffs’ attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Correvio Pharma Corp. (“Correvio” or the “Company”), analysts’ reports and advisories about the Company, interviews with former employees of the Company, U.S. Food and Drug Administration (“FDA”) briefing documents, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Correvio securities between September 5, 2018 and December 10, 2019, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.¹

2. Correvio is a small specialty pharmaceutical company that purportedly engages in developing therapeutics worldwide. The Company’s portfolio includes, among other products,

¹ Defendants are: Correvio Pharma, Corp., Mark H.N. Corrigan, William Hunter, Justin A. Renz, and Sheila M. Grant.

intravenous vernakalant (“vernakalant IV”), also referred to by Correio as Brinavess, for the rapid conversion of recent onset atrial fibrillation (“AF” or “AFib”) to sinus rhythm (“SR”).² Brinavess is intravenously delivered, and is a pharmacological converting agent designed to terminate an atrial fibrillation episode converting the heart back into normal rhythm. Its purported mechanism of action involves the selective blockade of multiple ion channels in the heart that are known to be active during episodes of AFib.

3. Defendants were focused on preparing a New Drug Application (“NDA”) to seek FDA approval to market and sell Brinavess in the United States during the Class Period. Brinavess was Correio’s most important product during the Class Period, and thus Brinavess’s FDA approval was the Company’s top priority during the Class Period. As Defendant Hunter, Correio’s CEO, acknowledged on multiple occasions, including on the Company’s March 13, 2019 earnings call, submitting the Brinavess NDA and obtaining FDA approval was “the most important thing” for Correio.

4. Correio’s NDA for Brinavess was primarily supported by a European post authorization safety study (also referred to as a “PASS” study) called “SPECTRUM.” As investors later learned, however, the SPECTRUM study did not adequately support Brinavess’s NDA, as Defendants concealed a number of glaring deficiencies with the study that precluded the NDA’s approval.

5. The SPECTRUM study was a required as a follow up measure after Brinavess was approved by the European Medicines Agency (the “EMA” or “European Commission”),

² AFib is the most common cardiac arrhythmia (abnormal heart rhythm). It is characterized by an erratic and often rapid heart rate where the electrical activity of the heart’s two small upper chambers (the atria) are not coordinated, resulting in inefficient pumping of blood and an increased risk of developing a blood clot in the heart, which could lead to embolic stroke. The sudden onset of AFib is often associated with rapid irregular palpitations, chest pain, shortness of breath and anxiety.

which is essentially Europe's equivalent to the FDA in the United States. The purpose of the SPECTRUM study was to obtain additional information regarding Brinavess's safety. Defendants conducted the study³ in Europe from 2011 until 2018.⁴

6. Brinavess has encountered many obstacles on the path to FDA approval. This is primarily because of Brinavess's highly risky safety profile. By way of background, a drug's safety profile is measured by a concept called therapeutic index. A drug's therapeutic index is the ratio between the dose that produces the desired effect to the dose that produces a toxic effect. Brinavess has an exceptionally narrow therapeutic index—meaning that, essentially, there is an extremely thin line between efficacy and toxicity. Brinavess has a therapeutic index

³ Correio outsourced the SPECTRUM study to a company called Quintiles. Under federal law, however, Defendants were still legally responsible for the conduct and oversight of the study. Pursuant to 21 C.F.R. § 312.3, a sponsor is responsible for the clinical investigation it initiates. Under FDA guidelines, a sponsor may transfer any or all of the sponsor's trial-related duties and functions to a contract research organization ("CRO"), such as Quintiles, "but *the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor.*" FDA Good Clinical Practice: Integrated Addendum to ICH (March 2018), *available at* <https://www.fda.gov/media/93884/download> ("FDA Good Clinical Practice Guide"). According to a former employee (CW1), Defendants were regularly updated about the study based on weekly or bi-weekly basis reporting from Quintiles. In addition to regular status updates, Defendants were also provided with interim safety reports, which they passed on to the EMA.

⁴ More specifically, SPECTRUM was an observational registry of Brinavess-treated patients in six countries in Western Europe, including Austria, Denmark, Finland, Germany, Sweden, and Spain. Patients who enrolled in the study received Brinavess at the discretion of their physicians independently of the study and were followed up to 24 hours after the last Brinavess infusion or until hospital discharge/end of medical encounter, whichever occurred first. All medical treatment was administered at the discretion of the physician. The study was initially designed to enroll patients and collect information prospectively with the first patient enrolled in September, 2011. However, because of the lower than anticipated enrollment rate partially driven by the lower than predicted use of Brinavess, the SPECTRUM study protocol was amended to allow for the enrollment of retrospective subjects to support timely completion of the study. This amendment was approved by the EMA in September, 2016 and allowed for retrospective enrollment at all sites as well as the addition of six new study sites. Retrospective data were collected only from patients who received Brinavess after additional risk minimization measures were implemented in April, 2013. The last patient was enrolled in April, 2018.

of 2.1, meaning that the toxic dose is only about two times the effective dose. In comparison, cocaine's therapeutic index ratio is about 15, morphine is about 70, and diazepam (Valium) is about 100.

7. Brinavess's regulatory history with the FDA began approximately fifteen years ago. On December 19, 2006, Correvio's former partner, Astellas Pharma US, Inc. ("Astellas"), submitted the first Brinavess NDA to the FDA. On December 11, 2007, the FDA's Cardiovascular and Renal Drugs Advisory Committee ("CRDAC") voted 6:2 to approve Brinavess for the rapid conversion of AFib to SR.⁵ In 2008, prior to granting marketing approval for Brinavess, the FDA agreed that Brinavess appeared to be effective in converting patients with AFib to SR, but on August 8, 2008, issued a letter to Astellas noting that the drug's safety profile was concerning, because eight adverse events ("AEs") had occurred during the drug's clinical studies. The FDA requested additional information on Brinavess's risks, and warned that "vernakalant needs to be extremely safe and its risks need to be well characterized prior to approval."⁶

8. In August 2009, Correvio's predecessor company, Cardiome Pharma Corp. ("Cardiome"), along with Astellas, announced that Astellas would undertake a single confirmatory additional Phase 3 trial ("ACT 5") under a Special Protocol Assessment in order to address the FDA's safety concerns. The ACT 5 study was initiated in October 2009. However, about a year later, around October 2010, an otherwise healthy 77 year-old with AFib and no

⁵ Any vote by the Cardiovascular and Renal Drugs Advisory Committee (CRDAC) is merely advisory. The FDA is not bound by any CRDAC vote.

⁶ FDA Briefing Document, Cardiovascular and Renal Drugs Advisory Committee Meeting (November 12, 2019) at 18, available at <https://www.fda.gov/media/133297/download> (the "FDA Briefing Document").

apparent underlying structural heart disease developed cardiogenic shock and died following a Brinavess infusion. On October 19, 2010, the FDA placed the Brinavess ACT 5 study on hold due to safety concerns.

9. Following this setback, Brinavess's development stalled for a number of years. In April 2009, Cardiome entered into two collaboration and license agreements with Merck to develop and commercialize Brinavess, which Merck terminated in September 2012 without having obtained FDA regulatory approval for the drug. In 2013, after Cardiome again assumed sponsorship of Brinavess, Defendants reinitiated discussions with the FDA regarding the regulatory path forward for Brinavess.

10. On November 18, 2013, the Company's predecessor, Cardiome, completed the acquisition of Correvio LLC, and its subsidiaries, as wholly owned subsidiaries.

11. Following completion of additional nonclinical studies in 2017, Cardiome proposed to resubmit a Brinavess NDA based on six years of accumulated safety data from sales of the drug in thirty-three countries, augmented by interim results from SPECTRUM. In 2017, the SPECTRUM study had enrolled over 1,100 patients, but enrollment was not yet complete.

12. In August 2017, the FDA notified Cardiome that the FDA's Cardioresenal Division did not agree that the data available at the time supported NDA resubmission.

13. On March 7, 2018, Cardiome underwent a reorganization and was re-formed as Correvio Pharma Corp.

14. In April 2018, Correvio announced that the Company had completed SPECTRUM's enrollment, with approximately 2,000 patients enrolled.

15. Following Correvio's request for a Type A meeting⁷ with the FDA, on June 11, 2018, the Company announced that the FDA provided Correvio with written correspondence regarding the regulatory path forward for Brinavess and agreed to schedule a Pre-NDA meeting.

16. The Class Period in this case begins on September 5, 2018, when Defendants announced that the full clinical study report for the SPECTRUM study was completed and reported preliminary results of the study. According to the Company, there were zero deaths reported and safety outcomes of interest were observed in 0.8% of cases.⁸ Over 70%⁹ of AFib episodes were successfully converted to sinus rhythm in a median time to conversion of 11 minutes.

17. In October 2018, Correvio met with the FDA to discuss the content and format of the NDA resubmission.

18. On October 23, 2018, Correvio announced that, based on "productive" pre-NDA discussions with the FDA, the Company planned to resubmit the Brinavess NDA during the second quarter of 2019. Correvio told investors that "the FDA agreed that no additional studies would be required for the resubmission of the NDA." Defendant Hunter further lauded that the SPECTRUM data would support the NDA, stating "we have learned from the FDA that it would be permissible to resubmit the NDA with the clinical and post-marketing surveillance data that we have already collected."

⁷ Type A Meeting is a meeting that is immediately necessary for an otherwise stalled drug development program to proceed. This type of meeting refers to meetings to resolve disputes, talk about clinical holds, special protocols.

⁸ At a 95% confidence interval: 0.5% - 1.4%. A confidence interval is the range of numbers that are X% likely to contain the correct answer. In other words, Correvio got 0.8% as their answer regarding safety outcomes of interest during the SPECTRUM trial, and can be 95% confident that the correct answer regarding safety outcomes of interest is between 0.5% and 1.4%.

⁹ 95% confidence interval: 68.1% - 72.2%.

19. On June 23, 2019, Correvio resubmitted the NDA to market Brinavess for the rapid conversion of AFib to SR (the “Resubmitted NDA”). To purportedly address the FDA safety concerns, Correvio included the results of the SPECTRUM study, as well as an analysis of spontaneous postmarketing adverse event cases reported from areas where Brinavess is approved for marketing.¹⁰

20. During the Class Period, Defendants touted the Company’s SPECTRUM study and its safety data, which Defendants claimed showed that Brinavess was safe and would support the Company’s Resubmitted NDA. For example, Defendant Hunter told investors on November 27, 2018 that the Resubmitted NDA “was based on extremely, [] impressive data that came of a 2,000 patient study in Europe called Spectrum, *which showed a really nice safety profile.*”

21. Based on such misrepresentations, Defendants raised \$25.5 million from unsuspecting investors during the Class Period. In January 2019, Correvio completed an offering that raised gross proceeds of US\$11.7 million. The Company completed another offering in August 2019, raising gross proceeds of US\$13.8 million.

22. Unbeknownst to investors, however, the Resubmitted NDA was not supported by sufficient safety data. The SPECTRUM study lauded by Defendants in fact suffered from a number of glaring deficiencies, none of which were disclosed to investors. For example, Defendants omitted that the SPECTRUM data contained a potential selection bias, which affected the validity of the study results.¹¹ In addition, the safety data from SPECTRUM was limited and misleading because adverse events were underreported, and basic, required information that should have been routinely collected was not, including critical information

¹⁰ Some of these thirty-three countries where Brinavess is approved for marketing include, *inter alia*, a number of countries in Europe, Canada, Argentina and South Africa.

¹¹ FDA Briefing Document, at 36.

such as blood pressure and heart rate data during patients' Brinavess infusions.¹² This data was required to be recorded under the SPECTRUM study protocol.¹³

23. These study deficiencies and missing data should have been known to Defendants because under the SPECTRUM study protocol, Defendants purportedly had quality assurance measures in place that mandated quality control teams to regularly review and audit the study's data.¹⁴ Under the protocol, Defendants were to be provided with reports and updates from quality control teams regarding SPECTRUM data, which should have included, *inter alia*, any missing such as heart rate or blood pressure readings or issues with adverse event reporting.¹⁵ Moreover, apart from the study protocol, Defendants were at all times responsible for the conduct, quality, and integrity of the study under applicable FDA regulations and guidelines. Thus, any Defendant who claims a lack of knowledge of SPECTRUM's problems and deficiencies during the Class Period was extremely reckless in not knowing.

24. Investors began to partially learn the truth about Brinavess's continued safety problems and the concealed problems and deficiencies of the SPECTRUM study in December 2019. The FDA scheduled an advisory committee ("AdComm") meeting to be held on December 10, 2019, led by the FDA's Cardiovascular and Renal Drugs Advisory Committee. The meeting was organized to focus on safety issues in evaluating Correvio's Resubmitted NDA. Specifically, the Cardiovascular and Renal Drugs Advisory Committee stated the purpose of the December 10 meeting was to review "whether the data provided by [Correvio] support the safety

¹² FDA Briefing Document, at 37.

¹³ SPECTRUM Study Protocol Incorporating Amendments 1 and 2, at 15 & 22-32 (August 3, 2016) (the "2016 Study Protocol"), *available at* https://clinicaltrials.gov/ProvidedDocs/29/NCT01370629/Prot_000.pdf.

¹⁴ *Id.* at 44-45.

¹⁵ *Id.*

and a favorable benefit-risk profile of vernakalant for the treatment of recent onset AFib. A secondary purpose of the Meeting [was] to consider whether a risk mitigation strategy could successfully identify patients at risk of poor [cardiovascular] outcomes following vernakalant administration.”¹⁶

25. On December 6, 2019, in advance of the AdComm meeting, the FDA released the committee’s briefing materials. The briefing materials stated that the committee did not believe that Brinavess’s benefits outweighed its risks. Specifically, the committee noted that Brinavess was associated with “serious liabilities” including low blood pressure, irregular heartbeats in the lower heart chambers, and death.¹⁷ On this news, Correio’s stock price fell \$0.86 per share, or 39.81%, to close at \$1.30 per share on December 6, 2019.

26. Then, on December 10, 2019, during pre-market hours, the Nasdaq Stock Market (“NASDAQ”) suspended trading in Correio securities in anticipation of the Cardiovascular and Renal Drugs Advisory Committee’s vote on whether to approve the NDA. Finally, just before market-close that day, the committee voted 11-2 against approval of Correio’s the Resubmitted NDA, noting that Brinavess’s benefit-risk profile was not adequate to support approval. Following this news, and after Correio shares resumed trading, Correio’s stock price fell \$0.94 per share, or 67%, to close at \$0.46 per share on December 11, 2019, further damaging investors. Correio’s stock price continued its downward slide the following day, dropping an additional \$0.07 per share to close at \$0.39 on December 12, 2019. The stock has not recovered.

¹⁶ FDA Briefing Document, at 14.

¹⁷ *Id.* at 40.

JURISDICTION AND VENUE

27. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

28. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

29. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Correvio securities trade on the NASDAQ, which is located within this Judicial District.

30. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

31. Plaintiff Clinton Atkinson, as set forth in the Certification filed at ECF No. 13-2, acquired Correvio securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

32. Plaintiff Nabil Saad, as set forth in the Certification filed at ECF No. 13-2, acquired Correvio securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

33. Plaintiff Iuliaa Mironova, as set forth in the Certification filed at ECF No. 13-2, acquired Correvio securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

34. Defendant Correvio is a Canadian corporation with principal executive offices located at 1441 Creekside Drive, 6th Floor, Vancouver, British Columbia, Canada V6J 4S7. The Company's common shares trade on the NASDAQ under the ticker symbol "CORV." On November 18, 2013, Cardiome completed the acquisition of Correvio LLC, a privately held pharmaceutical company headquartered in Geneva, Switzerland. As a result of the transaction, Cardiome acquired or incorporated a number of wholly-owned subsidiaries.¹⁸ Correvio was incorporated on March 7, 2018, under the laws of the Canada Business Corporations Act, in connection with an agreed reorganization of Cardiome. On March 19, 2018, Correvio entered into an agreement with Cipher Pharmaceutical, Inc., and Cardiome. Under the agreement, Cipher acquired Cardiome's Canadian business portfolio, and Correvio acquired all of Cardiome's pre-transaction assets and assumed liabilities, excluding the Canadian business portfolio. Correvio obtained a substitution listing on the NASDAQ and on the Toronto Stock Exchange and assumed Cardiome's reporting obligations.

35. Defendant Mark H.N. Corrigan ("Corrigan"), M.D., has served as Correvio's Chief Executive Officer ("CEO") since March 2019. Corrigan became a director at the Company on June 22, 2015. Corrigan has nearly 30 years of pharmaceutical research, development and regulatory experience in both the U.S. and international markets. He has been involved in the successful development and approval of numerous branded drugs during his career, including Zyvox®, Rescriptor®, Corvert®, Mirapex®, Lunesta®, Camptosar®, Xalatan® and Xopenex®, among others. Prior to joining Correvio's Board in 2015, Corrigan served as President and Chief Executive Officer of Zalicus Inc. Prior to that, he served as

¹⁸ Cardiome acquired or incorporated: Correvio LLC, Murk Acquisition Sub, Inc., Correvio International S.a.r.l., Correvio GmbH, Correvio Italia S.r.l., Correvio AB, Correvio, Correvio Spain S.L.U., Correvio Belgium S.p.r.l., Correvio (UK) Ltd., Correvio (Australia) Pty Limited.

Executive Vice President, Research and Development at Sepracor Inc. (now Sunovion Pharmaceuticals). Prior to joining Sepracor, Corrigan spent 10 years with Pharmacia & Upjohn, Inc., culminating as Group Vice President of Global Clinical Research and Experimental Medicine. He currently serves on the Boards of multiple life science companies, including Novelion Therapeutics, Nabriva Therapeutics AG, and Tremeau Pharmaceuticals. Corrigan previously served on the Board of Cubist Pharmaceuticals prior to their acquisition by Merck. He holds a B.A. and an M.D. from the University of Virginia and received specialty training in psychiatry at Maine Medical Center and Cornell University.

36. Defendant William Hunter (“Hunter”), M.D., served as Correvio’s CEO since before the start of the Class Period (July 2012) until March 2019. Hunter served as Correvio’s President from 2012 until his resignation in January 2019. During his tenure at the Company, Hunter served as a member of the Special Committee in charge of communications with the FDA regarding the Resubmitted NDA. Prior to working at Correvio, Hunter co-founded and served as President and Chief Executive Officer of Angiotech Pharmaceuticals (1992-2011). Hunter currently also serves as President and CEO of Canary Medical, a company that utilizes implanted sensor, battery and transmission technology to create “smart” implanted medical devices that can “self-report” on function, activity, wear, complications and patient outcomes for up to 20 years. Hunter currently serves as a director of Rex Bionics Plc, SummatiX Plc and Adherium Plc. Hunter received his BSc from McGill University and his MSc and MD from the University of British Columbia. Hunter has also served as a practicing physician in British Columbia and has over 200 patents and patent applications to his name.

37. Defendant Justin A. Renz (“Renz”) has served as Correvio’s Chief Financial Officer (“CFO”) between May 2017 and December 2018. Renz became a director at the

Company on May 16, 2017, and became its President in January 2019. Prior to joining Correvio, Renz served as Executive Vice President, Chief Financial Officer and Treasurer at Karyopharm Therapeutics from August 2014 to April 2017. Prior to Karyopharm, Renz was Executive Vice President, Chief Financial Officer and Treasurer at Zalicus Inc. (formerly CombinatoRx, Inc.), which he joined in September 2006. Prior to Zalicus, Renz served in senior finance and accounting roles at Serono, Inc. and Coley Pharmaceutical Group, Inc. Earlier in his career, Renz held finance positions at ArQule, Inc. and Millipore Corporation. Renz began his career with Arthur Andersen LLP in 1993. He received a Bachelor of Arts in Economics and Accounting from the College of the Holy Cross, a Master of Science in Taxation from Northeastern University and a Master of Business Administration from Suffolk University.

38. Defendant Sheila M. Grant (“Grant”) has served as Correvio’s Chief Operating Officer (“COO”) since March 2013 and is responsible for overseeing Correvio’s regulatory and manufacturing operations. Grant has been a director of the Company since August 1, 2003. Prior to Grant’s COO role, Grant was Correvio’s VP of Product Development, and was responsible for the overall management of the Brinavess program and oral development programs from pre-clinical studies through to commercialization. Grant also previously served as Director of Business & Clinical Development at Correvio. Prior to joining Correvio, Grant acted as a business consultant to De Novo Enzyme Corporation and Coopers & Lybrand. Grant also worked in research and development, production, and quality assurance with Schering Agrochemicals U.K., Wellcome Biotechnologies U.K. and Serono Diagnostics U.K., respectively. Grant holds an MBA degree from Simon Fraser University and an MSc from the London School of Hygiene and Tropical Medicine.

39. Defendants Corrigan, Hunter, Renz and Grant are sometimes referred to herein as the “Individual Defendants.”

40. The Individual Defendants possessed the power and authority to control the contents of Correvio’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Correvio’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Correvio, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background: Correvio’s Business

41. Correvio is a specialty pharmaceutical company. Correvio (formerly known as Cardiome Pharma Corp. prior to March 7, 2018) began as a research and development company based in Vancouver, British Columbia, Canada.

42. Correvio is a small Company. According to the Company’s 2018 annual report, as of December 31, 2018, the Company had approximately 138 employees located in various countries in Europe, Chadds Ford, Pennsylvania, and Vancouver, British Columbia.

43. The Company’s 2018 annual report states that Correvio has two marketed, in-hospital cardiology products, AGGRASTAT and BRINAVESS. In addition, the Company has licensed the marketing rights to the following products: ESMOCARD® and ESMOCARD

LYO®; a pre-registration drug/device combination product, TREVYENT®; a European-approved antibiotic, XYDALBA; and a cephalosporin antibiotic, ZEVTERA®/MABELIO®.

44. According to the Company's 2018 annual report, a key element of Correvio's core business strategy during the Class Period included "[s]uccessfully obtaining approval for vernakalant [aka Brinavess] worldwide." The Company's annual report told investors, "[w]e plan to file an NDA in the United States in the second quarter of 2019 and to continue to advance the approval and development of vernakalant (IV) elsewhere. We intend to pursue a regulatory strategy to further develop intravenous vernakalant in order to achieve its maximum potential in the treatment of acute forms of atrial fibrillation."

Vernakalant IV ("Brinavess")

45. Brinavess (vernakalant IV) is a novel antiarrhythmic agent which is available in an intravenous formulation in many parts of the world, but it is not available in the U.S. The drug is designed for rapid termination of acute onset AFib in a patient with no or minimal heart disease and some forms of structural heart disease including stable coronary heart disease, left ventricular hypertrophy, or mild heart failure.

46. AFib is the most common cardiac arrhythmia (abnormal heart rhythm). It is characterized by an erratic and often rapid heart rate where the electrical activity of the heart's two small upper chambers (the atria) are not coordinated, resulting in inefficient pumping of blood and an increased risk of developing a blood clot in the heart, which could lead to embolic stroke. If a blood clot in the atria leaves the heart, enters the circulation, and becomes lodged in an artery in the brain, a stroke may result. Approximately 15% of all strokes occur in people with AFib. The risk of developing AFib increases with age. The lifetime risk of developing AFib at age 55 has been estimated at 24% in men and 22% in women. In addition, during the

past 20 years, there has been a 60% increase in hospital admissions for AFib independent of changes in known risk factors. Third party research estimates that 5.5 million patients are treated for atrial fibrillation in the seven leading industrialized nations each year.

47. Brinavess is a chemical entity designed to treat AFib by converting the heart back into normal sinus rhythm (SR).

48. Brinavess was approved in the European Union in September 2010 and is registered and approved in over 40 countries (not including the U.S.) for the rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults, for non-surgery patients with AFib of seven days or less and for use in post-cardiac surgery patients with AFib of three days or less.

Brinavess's Turbulent Past: Death & FDA Rejection

49. In December 2006, the Company's predecessor, Cardiome, and its partner, Astellas, filed an NDA for Brinavess with the FDA. In August 2008, Astellas informed investors that it received an action letter from the FDA, informing Astellas that the FDA had completed its review of the Brinavess NDA, but the agency had requested additional information associated with the risk of adverse events experienced by a subset of patients during the clinical trials, as well as a safety update from ongoing or completed studies of Brinavess, regardless of indication, dosage form, or dose level. The letter further indicated that if the response to FDA requests was not satisfactory, additional clinical studies may be required.

50. In August 2009, Cardiome and Astellas, announced that Astellas would undertake a single confirmatory Phase 3 clinical trial, ACT 5, under a Special Protocol Assessment. The decision to conduct another trial was reached following extended discussions between Astellas and the FDA to define the best regulatory path forward for Brinavess. In October 2009, ACT 5 began enrollment of recent onset AFib patients without a history of heart failure.

51. In October 2010, the FDA placed a full clinical hold on the ACT 5 study, citing unreasonable and significant risk of illness or injury to human subjects. A patient in ACT 5 who received Brinavess experienced cardiovascular collapse with pulseless electrical activity (PEA) shortly following the Brinavess infusion and subsequently died. When investors learned of the clinical hold, Cardiome's stock sank 25% in premarket trading on October 21, 2010.

52. On December 15, 2011, the FDA met with the applicant (Merck at that time)¹⁹ to discuss removal of the clinical hold based on more stringent inclusion/exclusion criteria and more intensive patient monitoring. At the time of this meeting, at least 15 cases of severe hypotension with and without bradycardia had been attributed to Brinavess in the phase 2 and 3 studies (in addition to the case that led to the clinical hold). The FDA Briefing Document in November 2019 revealed for the first time that the FDA had concluded in 2011 that:

We do not believe that you have identified either a definitive mechanism or root cause of these episodes of vernakalant-induced severe hypotension and/or clinical shock and do not believe that your proposed modifications to the eligibility criteria are adequate to assure that such events will not recur in another trial . . . if the risk of hypotension and shock could not be adequately mitigated, further clinical development of vernakalant for parenteral administration could continue only if you redesign the program so that its aim is to establish an effect on a clinical outcome commensurate with this risk.²⁰

53. In 2013, Merck transferred sponsorship of Brinavess back to Cardiome. Thereafter, Cardiome initiated discussions with the FDA to determine the next steps for developing intravenous Brinavess in the United States.

¹⁹ In April 2009, the Company entered into two collaboration and license agreements with Merck for the development and commercialization of Brinavess, which Merck subsequently terminated in September 2012.

²⁰ FDA Briefing Document, at 18 (emphasis added). Unless otherwise indicated, all emphasis is added.

54. As revealed in the FDA Briefing Document, in February, 2014, Cardiome requested that the FDA lift the clinical hold. In response, the FDA reiterated the concerns it raised at the December 15, 2011 meeting and additionally expressed concerns about findings in an animal study Cardiome had conducted in the interim. In this study, rapid ventricular pacing was used to induce left ventricular dysfunction in dogs followed by an infusion of Brinavess. One of the six dogs became unstable post-infusion and died. Because of these concerns and the new data from the animal study, the FDA requested an additional study evaluating Brinavess in an animal model of AFib.²¹

55. The FDA Briefing Document also revealed that Cardiome consequently conducted a study in dogs to investigate the mechanism of hypotension.²² Based on the findings from these dog studies, Cardiome proposed resuming clinical studies and mitigate the risk of severe hypotension by: (1) excluding patients with heart failure (HF); (2) infusing 500 mL of saline prior to administering Brinavess; and (3) slowing the rate of infusion.²³

56. The FDA stated that the dog study results were not “particularly reassuring,” given the exposure-response data and the death of the only dog intended to model the human situation of Brinavess administration in the setting of tachycardia caused by AFib.²⁴

57. The FDA also concluded that there was insufficient evidence to conclude that the Company’s risk mitigation proposal would adequately assure the safety of subjects in clinical studies of Brinavess. The FDA indicated that merely demonstrating that Brinavess decreases the time to conversion from AFib to SR would not be an adequate clinical benefit to offset the risk of

²¹ *Id.*

²² *Id.*

²³ *Id.* at 19.

²⁴ *Id.*

even an infrequent occurrence of life-threatening hypotension; additional evidence of the drug's safety was needed.²⁵

58. Following completion of additional nonclinical studies in 2017, Cardiome proposed resubmitting the NDA based on six years of accumulated safety data from sales of Brinavess in thirty-three countries, together with interim results from the SPECTRUM study, which had not yet completed enrollment.

59. Defendant Hunter told investors on Cardiome's conference call held on August 12, 2017:

The FDA recently requested that we file all BRINAVESS clinical data that we had accumulated since our launch in Europe. We've requested a Type A meeting with written feedback and the FDA has agreed to this process.

We provided the FDA with our preferred path forward and anticipate feedback from the agency by the end of September. We look forward to providing you with an update on this process in the very near future.

60. In August 2017, Cardiome received the FDA's Cardioresenal Division response indicating that they did not agree that the data supported NDA resubmission. In an August 21, 2017 press release, Cardiome stated:

"In our most recent communication with the FDA, we proposed resubmission of the NDA based upon the original file and six years of accumulated safety data from sales of BRINAVESS in thirty-three countries, augmented by interim results from over 1,100 patients enrolled in the SPECTRUM study, a prospective post-authorization European Union safety study, along with pre-clinical data from subsequent studies the Company completed at the FDA's request," said William Hunter, MD, CEO and President of Cardiome. "We are disappointed that the Agency did not find these data compelling enough to recommend a resubmission, especially when several regulatory bodies in major jurisdictions around the world, including Canada in March 2017, have found the drug to be safe and effective. We will continue to have a dialogue with the FDA as we review our regulatory options."

²⁵ *Id.* at 19-20.

Cardiome believes the clinical trial and commercial experience with BRINAVESS(R) demonstrates that it is a best-in-class, fast-acting, atrial fibrillation converting agent and it intends to explore every reasonable avenue available to make Vernakalant available in the United States.

61. In April 2018, Correio announced that it had completed enrollment of the 2,000 patient SPECTRUM study.

62. Following a request for a Type A meeting with the FDA, in June 2018, Correio received a written response from the FDA regarding the regulatory path forward. According to the Company, the FDA informed Correio that it would be permissible to resubmit the Brinavess NDA and agreed that the Company could schedule a Pre-NDA meeting.

63. In October 2018, Defendants met with the FDA to discuss the content and format of the NDA resubmission. On October 23, 2018, Correio announced that, based on productive pre-NDA discussions with the FDA, the Company planned to resubmit the Brinavess NDA during the second quarter of 2019. Correio told investors that “[t]he FDA agreed that no additional studies would be required for the resubmission of the NDA.” Defendant Hunter praised the pre-NDA meeting and the clinical data underlying the NDA resubmission that provided “a clear path forward.”

64. On June 23, 2019, Correio resubmitted its NDA to market Brinavess for the rapid conversion of AFib to SR. The NDA was largely based on the results of the SPECTRUM study, which Defendants claimed would address the FDA’s serious safety concerns. Defendants also included an analysis of spontaneous postmarketing adverse event cases reported from areas where Brinavess is approved.

The SPECTRUM Study

65. While Brinavess is not approved for sale in the U.S., it is in Europe. SPECTRUM was a post-authorization observational study of Brinavess in Europe, designed to collect

information about dosing and to quantify risks associated with the use of the drug in real-world clinical practice. The SPECTRUM study was required by the EMA as a condition of the EMA's approval of Brinavess for rapid cardioversion of recent onset AFib in 2010. The study was conducted in six countries in Western Europe, including Austria, Denmark, Finland, Germany, Sweden, and Spain. Patients who enrolled in the study received Brinavess at the discretion of their physicians independently of the study, and were followed up to 24 hours after the last Brinavess infusion or until hospital discharge/end of medical encounter, whichever occurred first. All medical treatment was administered at the discretion of the patient's treating physician.

66. The SPECTRUM study commenced in August 2011, with the first patient enrolled in September 2011. During this time, Merck owned the development rights to Brinavess and contracted with Quintiles, now called IQVIA, a contract research organization ("CRO"), to conduct the study.²⁶ Merck, the sponsor at the time, was responsible for the initiation of the SPECTRUM clinical investigation. 21 C.F.R. § 312.3. FDA guidelines state that where a sponsor contracts with a CRO to conduct a study that will become the basis for seeking FDA marketing approval, the sponsor bears "*the ultimate responsibility for the quality and integrity of the trial data.*"²⁷

²⁶ Under federal regulations a CRO is defined as "a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration." 21 C.F.R. § 312.3.

²⁷ FDA Good Clinical Practice Guide states in relevant part:

5.2 Contract Research Organization (CRO)

5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, *but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor.*

67. On June 14, 2013, responsibility for the SPECTRUM study was transferred to Cardiome after Merck transferred Brinavess rights back to the Company.²⁸ Under the 2016 Study Protocol, the parties agreed that Correvio was responsible for reviewing and approving Quintiles management of the SPECTRUM study.²⁹

68. In September 2016, because of the lower than anticipated enrollment rate partially driven by the lower than predicted use of Brinavess, Cardiome amended the SPECTRUM study protocol, with the EMA's approval, to allow for the enrollment of retrospective subjects (rather than only prospectively enrolled subjects) to support timely completion of the study (the "2016 Study Protocol"). Retrospective data were collected only from patients who received Brinavess after additional risk minimization measures were implemented in April, 2013.

69. The 2016 Study Protocol remained in effect at all times relevant hereto. It stated that the responsible sponsor (Company) contacts were: Defendant Grant, COO; Dr. Kiran Bhirangi, Head of Medical Affairs and; Lucy Brindle, SPECTRUM study manager.³⁰

70. The 2016 Study Protocol stated that all serious adverse events (SAEs) and health outcomes of interest (HOIs) were to be reported to the CRO within 24 hours. Further, the protocol mandated that once the investigator (physician) reported a serious adverse event, the CRO was to immediately transmit the serious adverse event report to the individual(s) listed on the contact information page of the site study binder. In other words, all serious adverse event

²⁸ This was reflected in the document history section of the Quintiles statistical analysis plan for SPECTRUM. IQVIA Statistical Analysis Plan (SAP) at 3 (April 23, 2018), *available at* https://clinicaltrials.gov/ProvidedDocs/29/NCT01370629/SAP_001.pdf.

²⁹ 2016 Study Protocol, at 43 ("The CRO will design and manage the study with input, review and approval by the Sponsor.")

³⁰ *Id.* at 3.

reports were required to be immediately transmitted to Defendant Grant, Dr. Kiran Bhirangi, and Lucy Brindle.³¹

71. In addition, the 2016 Study Protocol called for interim reports to be provided to the Committee for Medicinal Products for Human Use with each periodic safety update report.³²

72. The 2016 Study Protocol also required that all study sites comply with a Pre-Infusion Checklist, which outlined, among other things, that the patient's blood pressure and heart rate was to be monitored during the Brinavess infusion, as well as for at least 15 minutes after the completion of the infusion.³³

73. The last patient was enrolled in SPECTRUM in April 2018, and SPECTRUM was completed on May 8, 2018.

74. Thereafter, Correvio began compiling the SPECTRUM data. When compiling data for a full clinical study report ("CSR") pharmaceutical companies generally have their quality control teams review the data to ensure its accuracy, integrity, and completeness. Correvio similarly had such quality assurance measures in place under the 2016 Study Protocol.³⁴ In addition, even prior to preparing the clinical study report, Correvio had a team of external advisors, known as the external safety review committee ("SRC"), responsible for reviewing interim and final reports of safety data and monitoring overall study progress.³⁵ The

³¹ *Id.* at 34.

³² *Id.* at 19.

³³ *Id.* at 15.

³⁴ *Id.* at 44.

³⁵ *Id.* at 45: "Specifically, the SRC will be responsible for (1) review of individual patient listings of serious adverse event (SAE) reports and aggregated data in the form of predefined tables and study result reports; (2) periodic assessment of subject accrual rate and study status; (3) evaluation on an *ad hoc* basis of any urgent safety issue identified by the Sponsor, CRO or the

SRC was responsible for convening “regularly-scheduled meetings of the SRC,” to review these interim and final reports and monitoring study progress.³⁶ These quality control teams should have flagged issues with underreported SAEs/AEs and missing required data, including information such as missing heart rate and missing blood pressure readings, that were only much later revealed to investors in the FDA Briefing Document.

75. On September 5, 2018, Defendants announced that the full clinical study report for the SPECTRUM study was completed, and reported preliminary results of the study. According to the Company, there were zero deaths reported and safety outcomes of interest were observed in 0.8% of cases. Over 70% of AFib episodes were successfully converted to sinus rhythm in a median time to conversion of 11 minutes. However, as detailed herein, Defendants omitted that the SPECTRUM study suffered from material problems and deficiencies and in fact under-reported serious adverse events.

Defendants Announce Correio’s Intent To Resubmit Brinavess’s NDA & Assured Investors The NDA Would Be Supported By SPECTRUM’s “Impressive” Safety Data

76. Throughout the Class Period, Defendants championed Brinavess’s safety profile based on, *inter alia*, the SPECTRUM data and claimed that this data supported the Resubmitted NDA’s approval. Based on Defendants’ representations regarding the SPECTRUM (PASS) data, Defendants claimed that the FDA did not require any additional studies to be submitted for NDA approval.

77. On October 23, 2018, Correio announced that, based on productive pre-NDA discussions with the FDA, the Company planned to resubmit the Brinavess NDA during the

SRC; (4) document and communicate in writing all SRC activities to Sponsor, and (5) adjudication of Health Outcomes of Interest (HOIs)/Serious Adverse Events (SAEs).”

³⁶ *Id.*

second quarter of 2019. Correvio told investors that “[t]he FDA agreed that no additional studies would be required for the resubmission of the NDA.” Defendant Hunter praised the pre-NDA meeting and the clinical data underlying the NDA resubmission that provided “a clear path forward.”

These communications, including our recent pre-NDA meeting, represent a significant milestone for Correvio, since *we have learned from the FDA that it would be permissible to resubmit the NDA with the clinical and post-marketing surveillance data that we have already collected*[.] . . . We are pleased with the collaborative nature of the FDA discussions that clarified a path forward for resubmission of the Brinavess NDA in Q2 2019, and we look forward to working closely with the FDA during the review process.

78. Following this announcement, on October 23, 2018, Correvio’s stock increased approximately 26% to close at \$3.93 per share.

79. Analysts were pleased to hear Correvio had additional data to support the resubmission, and based on Defendants’ representations regarding that data, believed that the Resubmitted NDA would be approved. For example, following Defendants’ announcement, analysts at Mackie Research opined in a report dated October 23, 2018:

Decent Probability of Being Approved: *We expect the FDA to approve Brinavess in 2020.* Our high expectation of the FDA approval is primarily due to: (i) the solid results of four well-controlled Phase III studies (ACT I, ACT II, ACT III and AVRO) that were used to support the European approval of the drug, (ii) *the positive results of the post-market SPECTRUM study that demonstrated the efficacy and safety of Brinavess in a real-world setting (in Europe)*, (iii) the reported cardiogenic shock (in the ACT-5 Phase III study conducted in South America) being a single and isolated case – the case of cardiogenic shock triggered a clinical hold on Brinavess by the FDA in 2010, and (iv) FDA’s ultrafriendly attitude towards new drug applications in recent years.

80. Similarly, analysts at H.C. Wainwright & Co. believed Defendants’ claim that the Resubmitted NDA was sufficient based on SPECTRUM data. As stated in the analyst report dated October 25, 2018:

Brinavess on track for resubmission in the US. On October 23, Corveio announced that it had received a green-light from the FDA to re-file Brinavess for US approval. *According to management, the FDA did not request any additional clinical, dose-finding, or retrospective studies*, and the company plans to resubmit the New Drug Application (NDA) in 2Q19. *In our view, this is a significant development for the company, and we believe that there is now a high probability that Brinavess could be approved in the US before the end of 2019.* Recall, back in 2008, the FDA rejected the Brinavess NDA despite a positive advisory committee recommendation, citing safety concerns regarding rare cases of severe hypotension and bradycardia. Since then, Brinavess has been approved in more than 40 countries and has been marketed in the EU from 2010. The company re-engaged with the FDA in 2017 and has been working together with the agency to map out a regulatory path forward for Brinavess in the US. *These efforts were aided by the release of positive results from the Phase 4 SPECTRUM post-marketing study evaluating the safety of Brinavess for the rapid conversion of recent onset atrial fibrillation (AF) in the EU in September. SPECTRUM enrolled 1,778 patients with 2,009 episodes of AF, and Brinavess successfully converted 70.2% of treated patients with a median time to conversion of 11 minutes. Furthermore, there were very few cases of severe adverse events reported in the study and zero patient deaths. Since the standard review period for a resubmitted NDA is six months, we believe that Brinavess could be approved by 4Q19 and could reach the market in 1Q20.*

81. On November 27, 2018, Defendants presented at the Piper Jaffray Healthcare Conference. During the conference, Defendant Hunter told investors the Company was “on track towards submitting an NDA” that was “based on extremely impressive data” that came from SPECTRUM, which showed a “really nice safety profile.” Defendant Hunter stated in relevant part:

So over the last little while we’ve had a number of really important events and I think to be quite honest with you the last six or seven months have probably been the most active in the company’s history.

We had some interesting news from the US FDA with respect to Brinavess, a drug that had and has been on clinical hold for a number of years in the US and *we are now on track towards submitting an NDA for the product in second quarter of the year*, which I’ll come back to. *That was based on extremely, an impressive data that came of a 2,000 patient study in Europe called Spectrum, which showed a really nice safety profile and a nice efficacy profile as well.*

Brinavess as I mentioned, we had a Type A meeting in June that allowed us to go forward with a pre-NDA meeting, which was scheduled for October. That

meeting happened in October. And during that meeting we've got to go ahead to submit our NDA, *that the data that we were in possession of would satisfy the needs for the NDA to be reviewed.*

Importantly, there were no additional studies that needed to be done, either of the clinical or record review nature, we had what we needed to do. That sets us up to file our NDA in the second quarter of 2019, because this is a re-filing, it should be a six-month review and meaning that we should have an answer from the agency prior to the end of 2019 with the potential to actually launch this product in the beginning of 2020.

We also have been doing work on the intellectual property position on this drug and believe that we will have a patent extension through 2031. So with a launch in 2020 and 2031 patent date, *we feel the product has a wonderful opportunity in front of it in the United States. Spectrum really set this up for us.* We had a 2,000 dose study, which was on 1,800 patients approximately 1,800 patients. Some of the patients were treated more than once. And we found that and we had a 70 plus percent efficacy rate for the drug, which is actually better than the clinical trials in Phase 3 that led to the approval of the drug in Europe. And that probably has to do a little bit with refining the patients that we give the drug to and using the drug for really acute onset first 48 hours first or second time presentation of AFib. *But importantly, we had no real safety issues whatsoever. We had no deaths reported in that study.*

And importantly if you look at the health outcomes of interest so cardiovascular effects were less than 1%, that is highly comparable and arguably better than what's seen with a lot of other treatments out there.

Defendants Continue To Tout Brinavess's Safety Profile Leading Up To Completing Correivo's ATM Offering

82. Defendants continued to reassure investors into 2019 that the NDA package was on track for approval based on SPECTRUM's data. In addition, in January 2019, Defendants announced a CEO succession plan that would purportedly further support the Resubmitted NDA. Defendant Corrigan was named to take over as CEO in Defendant Hunter's place. The Company's January 2, 2019 6-K stated in relevant part:

Mark H.N. Corrigan, MD, a current member of the Company's Board of Directors, has been named Correivo's next Chief Executive Officer. William Hunter, MD, after a successful 6-year tenure as President and Chief Executive Officer, will transition out of his current role by the end of the first quarter of 2019. Dr. Hunter will remain a member of the Company's Board of Directors.

Dr. Corrigan is a seasoned life sciences executive who brings to Correvio nearly 30 years of pharmaceutical research, development and regulatory experience in both the U.S. and international markets. He has been involved in the successful development and approval of numerous branded drugs during his career, including Zyvox®, Rescriptor®, Corvert®, Mirapex®, Lunesta®, Camptosar®, Xalatan® and Xopenex®, among others.

...

“When I accepted the role of CEO in 2012, my top priorities were to build a commercial team to launch Brinavess® in Europe ***and complete SPECTRUM, a very successful study that has now helped us move forward with the U.S. FDA,***” said Dr. Hunter. ***“Now that those objectives have been achieved, I am handing operations over to the person most qualified to take the important next steps of getting Brinavess approved and launched in the U.S.”*** Having worked closely with Mark for several years as a member of our Board, I am confident that he is the right person to continue the strong momentum we have created. It has been a privilege to lead Correvio these past years and I look forward to continuing my engagement with the Company as a member of the Board and working with Mark and the entire leadership team over the next few months to ensure a smooth transition.”

...

In addition to the CEO succession plan, Correvio announced that Justin Renz, Chief Financial Officer of Correvio, will also assume the responsibilities of President.

83. Analysts praised the succession plan and believed the forthcoming NDA was on its way to acceptance in light of the purportedly “very successful” SPECTRUM study. Analysts from H.C. Wainwright & Co. stated in a report dated January 14, 2019:

Brinavess’s NDA re-submission on track for 2Q19. In October 2018, Correvio announced that the FDA has agreed for the company to re-submit the Brinavess new drug application (NDA) for US approval for the treatment of atrial fibrillation (AF). ***Since then, the company has been preparing the NDA to include the latest real-world data such as the results from the 1,778-patient SPECTRUM post-authorization study in Europe, and we expect the company to file the NDA in 2Q19.*** Considering the standard review period for a resubmitted NDA is six months, we believe that Brinavess could be approved by 4Q19 and could reach the market in 1Q20. Furthermore, ***we believe that this time Brinavess has a high probability of FDA approval because since 2008, when FDA last rejected Brinavess on safety grounds, it has been approved in over 40 countries and has been safely used in thousands of patients without additional complications. In the SPECTRUM study, Brinavess was able to convert 70.2%***

of patients with a medial time to conversion of 11 minutes, compared to a 4-6 hour hospital stay for standard of care electrical cardioversion.

...

Management change with an eye towards success. On January 2, Correvio announced that Dr. William Hunter, President and CEO, will step down from his roles by the end of 1Q19 to be succeeded by Dr. Mark Corrigan, who is currently a member of the company's Board of Directors. In our view, *this planned succession could help bring additional experience, particularly in the area of successfully getting Brinavess approved and launched in the US.*

84. On January 17, 2019, Correvio announced the completion of all sales of common shares qualified under its July 10, 2018 at the market offering. Correvio reported that 4.8 million shares of common stock sold at an average price of US\$2.71 per share, resulting in gross proceeds to the Company of US\$11.7 million.

Defendants Continue To Hype Brinavess's NDA And SPECTRUM Data

85. On a March 14, 2019 earnings call, Defendants touted SPECTRUM's "positive data," the Resubmitted NDA's completeness without additional studies, and the great financial success the Company would experience once the NDA was accepted in 2019:

DEFENDANT RENZ: Following productive pre-NDA discussions with the U.S. Food and Drug Administration, we plan to resubmit the Brinavess New Drug Application during the second quarter of 2019. *The FDA's decision to allow this resubmission was partially driven by the positive data generated from SPECTRUM, a post-authorization safety study conducted in the EU evaluating Brinavess in over 2,000 treatment episodes of atrial fibrillation, which I will go into more detail about in a few minutes.*

...

As previously mentioned, following our discussions with the FDA in October, we intend to resubmit the Brinavess NDA during the second quarter of 2019. As you know, Brinavess or vernakalant is an intravenous antiarrhythmic indicated for the rapid conversion of recent onset atrial fibrillation in patients without significant heart failure. *Importantly, the FDA did not request any additional studies in order to resubmit the NDA.* We expect that the regulatory review period for Brinavess will be approximately 6 months. So it's possible we could receive an FDA approval decision during the fourth quarter of 2019.

I'd also like to highlight that in support of our NDA application, *we are now in a position to share with the FDA over 8 years of real-world experience from the aforementioned 55,000 treated patients. Preliminary post-marketing surveillance data from the SPECTRUM study was made available to the FDA as part of our pre-NDA discussions.*

We have a summary of the preliminary data from the SPECTRUM study. SPECTRUM was conducted as part of the follow-up measures agreed to with the European Medicines Agency in 2010.

...

With respect to safety results, the cumulative incidence of health outcomes of interest defined as the – as significant hypotension, ventricular arrhythmia, atrial flutter or bradycardia were reported in only 0.8% of patients. 28 serious adverse events were reported for 26 patients, and no deaths were reported in the study.

...

DEFENDANT HUNTER: *Looking forward, the most important thing this company will do is file that NDA, have that NDA accepted and ideally move on to approval before the end of the year.*

...

So if you just look at the minuted history of the drug, it goes back many, many years as you can probably appreciate. And it's got a lot of history and nuance and elements to it. And so that's probably the biggest issue. It's probably the reason our stock isn't a lot higher than it is or probably should be, quite frankly. And – so that's it. *And I believe as we continue to derisk the regulatory pathway and last year was a huge step in doing that. I mean, SPECTRUM getting us to the NDA, the pre-NDA meeting getting to go ahead to file the NDA, that was, I think created immense value. And I think once that NDA is filed, I think once that NDA is accepted, and now you're into final stretch of review, that will derisk the asset an awful lot. So that's where we're focused on. That's where, I think, the money is in 2019.*

86. Also on March 14, 2019, Defendants announced an offering permitting the Company from time to time sell, through “at-the-market” offerings on NASDAQ.

87. Analysts absorbed Defendants' representations and continued to be pleased by Defendants' reassurances regarding the NDA's supporting data. Analysts from H.C. Wainwright & Co., were satisfied that the Resubmitted NDA remained on-track to be filed in Q2 2019, as stated in a report dated March 15, 2019:

According to management, the company is in the process of preparing the Brinavess data package and remains on-track to resubmit the new drug application (NDA) for US approval in 2Q18 [sic]. In our view, the FDA's acceptance of Brinavess NDA and the drug's potential US approval before the end of 2019 are the most important upcoming catalysts for the company. *The NDA is expected to be supported by the positive safety and efficacy results from the 1,778-patient SPECTRUM post-approval study conducted in Europe as well as several investigator-sponsored studies of Brinavess. Recall, Correvio announced positive topline results from SPECTRUM in September 2018, which showed a 70.2% successful conversion rate in a median time of eleven minutes, a 1% severe adverse event rate, and zero patient deaths. In our view, Brinavess has a high probability of FDA approval based on the strength of the clinical data and as well as what appears to be a more favorable view of the drug at the agency.*

88. On Correvio's May 8, 2019 Q1 2019 earnings call, analysts attempted to drill down on what else Correvio needed to do in order to resubmit the NDA. Defendant Corrigan responded that the Company was to include additional data from two additional studies Correvio did not include in the original NDA. Defendant Corrigan praised the safety data the Company was working on integrating into the NDA:

ANALYST: Mark and Justin, I just have quick questions for me. *Regarding Brinavess, I know you stated that you are planning to submit it this quarter. Is - - what's left in trying to get done before submitting it? Is it just the administrative stuff?* And based on your conversations previously now going into this resubmission, do you have a feel for whether it's going to be a real 6- month review or it could be even less than that?

DEFENDANT CORRIGAN: That's the question we're talking about that yesterday. You must have ears on the walls here. Let me take the first one. In the pre-NDA meeting, *we discussed with the FDA what the data groupings they'd like to see. And they prompted the inclusion of 2 studies that weren't in the original file. So part of that has been the inclusion of those 2 studies.* And secondly, the -- *this is really about the writing and integrating data* process. So this is pretty standard NDA assembly, I would say, and time lines, which, of course, then there's allowable period for publishing. So it's -- when I look at it, what's different about it fundamentally is really bringing forward real-world experience. *If you think about it, in addition to the clinical trials, which would -- were part of the original NDA, we're adding 3 major data sets to this, okay? SPECTRUM study, number one. Number two, there have been 2,000 patients treated in really several states, more than 20 studies by investigator-initiated studies, which provide a pretty interesting data set. While not all combinable,*

but certainly under clinical research conditions that vary from randomized clinical trials to observational studies, but provides another 2,000 patients in the study condition that, I think, are relevant. And then lastly, the periodic safety update reports on the 55,000 patients treated is an important third element. So those are the 3 major data elements that speak to the safety and efficacy profile in real-world that have to be integrated to the NDA. Turning now to your second question. I have -- I don't think it will be less than 6 months. While they certainly have seen that first part of the NDA, I think they're going to consider carefully the rest. And in general, the FDA is pretty overburdened. And so I think they will look at this very carefully. That's what we've asked them to do. And I think that I would be pleasantly surprised with an earlier decision, but that's not what we're counting on.

Defendants Tout Correvio's Resubmitted Brinavess NDA Leading Up To Yet Another Offering

89. On June 24, 2019, Correvio announced it had resubmitted its NDA to the FDA seeking approval for Brinavess. Defendants touted the resubmission and its supposed support from the SPECTRUM data. Defendant Corrigan stated:

The resubmission of the Brinavess NDA is a major milestone for Correvio and is the culmination of substantial effort by our employees and the investigators who have dedicated themselves toward investigating this potential new treatment option for adult patients with recent onset AF[.]

...

*The NDA is supported by data from SPECTRUM, a post-approval safety study that was conducted in Europe which evaluated 1,778 unique patients across a total of 2,009 treatment episodes following administration of Brinavess. The SPECTRUM data demonstrated that treatment with Brinavess successfully converted 70.2% of all treated AF patients into normal sinus rhythm. In addition, treatment with Brinavess showed a median time to conversion of 11 minutes from the start of the first infusion among patients who successfully converted. **The cumulative incidence of health outcomes of interest (defined as significant hypotension, ventricular arrhythmia, atrial flutter, or bradycardia) were reported in 0.8% of patients. Twenty-eight serious adverse events were reported in 26 of the 1,778 patients and no deaths were reported in the study.** In addition to SPECTRUM, the Brinavess NDA is also supported by nine Phase 3 and Phase 2 clinical trials and over eight years of real-world experience in approximately 50,000 treatment patients worldwide.*

90. Analysts absorbed Defendants' assurances regarding the SPECTRUM data and believed that based thereon, the Resubmitted NDA was sufficient. Analysts at H.C. Wainwright & Co. stated:

Brinavess NDA resubmitted as expected. On June 24, management announced that the company has resubmitted the Brinavess NDA to the Food and Drug Administration (FDA) for the treatment of acute onset atrial fibrillation (AF) as planned. With this filing, the company is now close to its goal of commercializing Brinavess in the US. Recall, back in 2008, the FDA rejected Brinavess application despite a positive advisory committee recommendation due to safety concerns regarding rare cases of severe hypotension and bradycardia. Additionally, the regulatory agency placed the then ongoing ACT 5 Phase 3 study on clinical hold due to an unexpected serious adverse event experienced by a treated patient in October 2010, and eventually the study was terminated in 2013. Since then, Brinavess has been approved in 41 countries and is currently marketed in 33 countries, including the UK, Germany, France, Canada, and South Africa. ***The resubmitted Brinavess NDA is supported by positive safety and efficacy data from the 1,778-patient, post-approval SPECTRUM study that was conducted in Europe. In addition to the SPECTRUM data, clinical data from nine Phase 3 and Phase 2 clinical studies and over eight years of real world experience in treating more than 50,000 patients worldwide were also included in the application. We believe Brinavess has a high probability of FDA approval based on the quality and amount of the clinical data as well as FDA's recent decision to reconsider the application without the need for an additional US clinical study.***

91. On July 25, 2019, Correio announced that the FDA had accepted the Resubmitted NDA for review. The FDA assigned a target action date of December 24, 2019 under the Prescription Drug User-Fee Act (PDUFA), and indicated that it would hold an advisory committee meeting to discuss the application. Defendant Corrigan stated:

The FDA's acceptance of this resubmitted NDA marks another important milestone for Correio and for the global Brinavess program[.] . . . ***As a potential new AF treatment, with a well-characterized efficacy and safety profile,*** we believe that Brinavess, if approved, will be an attractive addition to the AF treatment landscape. We look forward to working with the FDA during the review process.

92. On August 1, 2019, Correio announced an overnight marketed underwritten public offering of common stock. On August 7, 2019, Correio announced the closing of the

public offering of 9.2 million common shares, sold at US\$1.50 per share, raising gross proceeds of US\$13.8 million.

Defendants Announce AdComm Date To Discuss Brinavess's Resubmitted NDA

93. On November 4, 2019, Correio announced that the FDA would hold a Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting in connection with its review of the pending NDA for Brinavess. The meeting was scheduled for December 10, 2019 from 8:00 a.m. to 5:00 p.m. ET.

94. The Company explained to investors that the Cardiovascular and Renal Drugs Advisory Committee panel's decision was non-binding on the FDA:

The CRDAC is an independent panel of experts that evaluates data concerning the efficacy and safety of marketed and investigational products for use in the treatment of cardiovascular and renal conditions and makes appropriate recommendations to the FDA regarding regulatory actions. Although the FDA considers the recommendations of the CRDAC, the final decision regarding pending regulatory actions for a product is made by the FDA; the recommendations by the panel are non-binding.

95. Analysts viewed the AdComm meeting "as a low-risk gating event" based on Defendants' previous positive representations regarding the SPECTRUM data. Analysts at Cantor Fitzgerald stated in a report dated November 4, 2019:

An AdCom date of 12/10/19 has been set for review of CORV's NDA for Brinavess (vernakalant hydrochloride, IV) with the FDA's Cardiovascular and Renal Drugs Advisory Committee (CRDAC). This is ahead of the 12/24/19 PDUFA date. **We continue to view the AdCom as a low-risk gating event ahead of expected approval**, and remind that in December 2007, CRDAC voted 6-2 in favor of recommending approval. The AdCom is a prudent step being taken by the FDA, in our view, before they can move towards approval. We think this makes sense given the large potential addressable patient population. Please refer to our recent initiation note here for more details on our expectations for this asset.

The NDA is supported by data from SPECTRUM, a post-authorization safety study that was conducted in Europe which evaluated 1,778 unique patients across a total of 2,009 treatment episodes. SPECTRUM demonstrated that

treatment with Brinavess successfully converted 70.2% of AF patients with a median time to conversion of 11 minutes from the start of the first infusion among patients who successfully converted. The NDA is also supported by nine Phase 3 and Phase 2 clinical trials and over eight years of post-marketing experience in EU in ~50K patients. ***We believe this best in-class data and experience will support Brinavess through approval and garner widespread uptake in the U.S. market.***

96. On November 14, 2019, Defendants held an earnings call to discuss Correvio's Q3 2019 financial results. During the call, analysts attempted to drill down on Defendants' expectations related to the AdComm meeting and how communications with the FDA were progressing as to the Resubmitted NDA. Defendant Corrigan dodged the question and focused only on the PDUFA date:

ANALYST: And going from China to the U.S., in terms of how the AdCom Panel has been set up for the December 10 and the PDUFA date just being 2 weeks from then, ***so what are the expectations there from the AdCom?*** How -- especially, would that somehow move the PDUFA date by any means? ***I'm just trying to get a feel for like how your conversations are going with the FDA on the file itself,*** independent of the AdCom recommendation.

DEFENDANT CORRIGAN: That's an excellent question, RK, and one that we discuss internally. I think this is really in the FDA's court. They've set up the dates. The dates are -- they have the opportunity to set the AdCom. It wouldn't be the first time that a PDUFA date has moved. I don't think that that's -- if we have a positive advisory committee and we are engaged with the FDA in discussions with regard to labeling, I will be very pleased and I will not despair over a slip in that PDUFA date. It is a very short window for them to construct labeling. You're right on target with that.

97. Analysts further attempted to determine the likelihood the AdComm would be positive based on the Resubmitted NDA's additional data. Defendant Corrigan again dodged the question, focusing only on speculating as to the FDA's reasoning for holding another AdComm:

ANALYST: Yes. So Brinavess vernakalant went through an ad com years ago, and the vote was 6:2 in favor of approving the drug. And I think the 2 dissenters said that they wanted more data. ***Now you've got that more data. I'm just wondering, in all likelihood, the ad com will come out positive. The last time the FDA voted -- or the FDA acted against the ad com recommendation, like why***

do you think the FDA wants an ad com again since they had a positive one the first time around?

DEFENDANT CORRIGAN: That's an excellent one. If you think about it administratively, we remain on clinical hold, and which means that the FDA doesn't believe it's safe to be studied in those conditions. And that's a long way from that to an approval for widespread public use, and I think that they -- again, so I think this is a -- it's a prudent step by the FDA to ensure, I believe, that the field truly wants the drug. *And now, in light of this new data, they can like listen to the field, express their views and, at that point, lift the clinical hold and move on the process towards approval. I do think that if we were not on clinical hold that they may not have required the ad com.*

Unbeknownst To Investors, The Resubmitted NDA Was Not Supported By Sufficient Safety Data Or An Adequate Risk Mitigation Plan

98. Unbeknownst to investors, the Resubmitted NDA was not supported by sufficient safety data from, among things, the SPECTRUM study. In addition, Correvio was required to submit a risk mitigation plan ("REM") with the Resubmitted NDA, but investors were unaware that Correvio's proposed REM was grossly insufficient to support the NDA and approval because, as revealed in the FDA Briefing Document, the Company apparently still did not understand the mechanism underlying Brinavess. In addition, the purported "pre-infusion checklist" was inadequate.³⁷ Defendants completely omitted any discussion of the REM and its importance to the application when they were hyping the Brinavess resubmission and SPECTRUM results.

99. During the Class Period, Defendants overpraised shoddy clinical SPECTRUM data. According to the FDA Briefing Document, the SPECTRUM data contained a potential selection bias to the design and conduct of SPECTRUM which affected the validity of the study results.³⁸ The committee noted the bias issues in four areas: (1) because physicians decided

³⁷ FDA Briefing Document, at 39.

³⁸ *Id.* at 36.

whether to administer Brinavess, it was possible that the physician was only administering the drug to healthier patients, as, for example, in the SPECTRUM study, fewer patients with heart failure or heart disease were enrolled than in the clinical trials; (2) there was evidence that not all patients were screened during the enrollment process and it was possible that certain patients with adverse events or health outcomes of interest were never screened or enrolled; (3) baseline characteristics were not obtained for those individuals who were not enrolled, and therefore there was no way to determine whether there were major differences between enrolled patients and those who were not enrolled and; (4) retrospective enrollment may have introduced bias, as retrospective enrollment of a patient was related to that patient's generally positive health outcome following Brinavess treatment.³⁹

100. In addition, the FDA briefing document revealed the safety data from SPECTRUM was limited and incomplete because required information, such as patients' heart rate and blood pressure data, was not consistently collected.⁴⁰ This information was required to be collected under the 2016 Study Protocol, which called for "monitoring of the patient for the duration of the infusion and for at least 15 minutes after the completion of the infusion for signs and symptoms of a sudden decrease in blood pressure or heart rate."⁴¹

101. Moreover, the incidence of serious adverse events (SAEs) and adverse events (AEs) were underreported. Similar to the earlier Brinavess clinical trials, 4% of Brinavess-treated patients in SPECTRUM did not convert to SR. As reflected in Brinavess's clinical trials, this 4% group was at higher risk of experiencing an SAE or AE, or negative health outcome of interest. The SPECTRUM study did not provide the reason why the patient was not treated with

³⁹ *Id.* at 36-37.

⁴⁰ *Id.* at 37.

⁴¹ 2016 Study Protocol, at 15.

another Brinavess infusion (i.e., because the patient may have been experiencing an adverse event) to determine whether the second dose would convert the patient to sinus rhythm. ***This crucial information was missing for 70% of patients in this at-risk subgroup.***⁴²

102. Further, Defendants' REM was wholly inadequate. The FDA noted in December 2011 that the Company's partner had not identified either a definitive mechanism or root cause of serious adverse event ("SAE") episodes of Brinavess-induced severe hypotension and/or clinical shock. In 2011, the FDA did not believe that the proposed modifications to the eligibility criteria were adequate to assure that such events would not recur. The FDA reiterated this to Cardiome in 2014. When Defendants resubmitted the NDA in 2019 they still did not understand Brinavess's mechanism (how the drug worked on a molecular level) and were therefore unable to provide adequate eligibility criteria to assure AEs and SAEs did not occur. Without knowledge of Brinavess's mechanism, Defendants could not prepare an adequate REM to avoid adverse events Brinavess caused.

103. Nonetheless, despite knowing that the SPECTRUM safety data was incomplete, unreliable, and that the Company still did not understand how the drug worked on a molecular level, Defendants repeatedly assured investors that strong safety data supported Brinavess's Resubmitted NDA. Moreover, Defendants claimed that the data was so solid that the FDA would not be requiring any additional clinical studies.

Former Employees Corroborate That Defendants Were Closely Involved With The SPECTRUM Study And Aware Of Significant Problems With The SPECTRUM Data

104. Confidential Witness ("CW") 1 worked at Cardiome in various roles, including: (1) clinical project manager; (2) associate director, clinical research; and (3) clinical research manager during two different tenures at Cardiome. From June 2002 to June 2004, CW1 was a

⁴² FDA Briefing Document, at 37.

clinical research manager, and from June 2004 to November 2005, CW1 was an associate director, clinical research. During 2002-2005, CW1 worked on Brinavess's Phase III study. CW1 reported to Defendant Grant and worked out of Cardiome's Canadian office.

105. During CW1's second tenure with Cardiome, from April 2013 to February 2018, CW1 was a clinical project manager out of Cardiome's UK office, and reported to Kiran Bhirangi, the vice president of clinical development and medical affairs, who worked out of the Company's Swiss office. During CW1's second tenure at the Company, CW1 was responsible for working on the SPECTRUM study.

106. CW1 reported that the SPECTRUM study was "contracted out to Quintiles." CW1 explained that SPECTRUM was "a fully-outsourced study," but CW1 was responsible for its oversight. CW1 noted that although it was an outsourced study, Cardiome was responsible for making important decisions regarding the SPECTRUM trial.

107. As a part of CW1's duties, CW1 spoke to representatives of Quintiles (the "CRO") about the SPECTRUM study "fortnightly – or weekly – via teleconference." These conversations often included the Quintiles project manager, a contract research agent ("CRA") and the lead data manager. CW1 was also responsible for overseeing the CRO and ensuring timeliness of operations, that the CRO was sticking to the rules and regulations, updating working documents, and tracking the study's progress. CW1 duties also included managing the CRO's concerns and necessities to keep the study on track, such as how to enroll more patients.

108. CW1 recalled that adverse events were reported by trial site and input into the safety and clinical databases. CW1 stated that Quintiles was responsible for ensuring the electronic data system was in place where the adverse events were tracked for the SPECTRUM study.

109. CW1 recalled that during the SPECTRUM study the CRO reported adverse events as well as serious health outcomes of interest (“HOIs”). CW1 noted that the EMA required Cardiome to track HOIs, but CW1 had “not seen this before or since in other trials.”

110. CW1 received progress reports from Quintiles that included information such as the number of enrollees in the study and how much data had been cleared. These progress reports were drafted weekly and were always provided before any management meeting, as the progress reports were needed to discuss progress and updates at management meetings.

111. CW1 was in charge producing reports based on CW1’s communications with the Quintiles project manager and sending those reports to Kiran Bhirangi, who would present to the reported information to the senior management team in Canada.

112. CW1 also spoke with Bhirangi about the SPECTRUM study weekly. During CW1’s calls with Bhirangi, CW1 provided him with study updates. CW1 also spoke with Bhirangi about problems with the study, such as certain sites not enrolling enough patients, or the need to change study protocols. CW1 updated Bhirangi on the number of adverse safety events and health outcomes of interest that had been reported.

113. CW1 recalled that CW1’s boss, Kiran Bhirangi, was responsible for regularly updating Correvio executives, including Defendant Grant, about the SPECTRUM study. CW1 stated that, “it [SPECTRUM] was a very expensive study, for a small company like that – *so the executives would have been kept up to date*, through Kiran [Bhirangi], my boss.” CW1 reported that executives were provided with, regular updates from Bhirangi based on up-to-date information from the CRO, in addition to, among other reports, annual safety reports and “any serious adverse events – according to ICH GCP [good clinical practice] guidelines.”

114. In addition, CW1 reported that the SPECTRUM study was running an interim safety report that was produced and sent to EMA for review. This interim report contained all the safety data collected to that date.

115. CW1 recalled that with SPECTRUM study, “the hope was they [the FDA] would see that it’s [Brinavess] safe and the clinical hold would be lifted.”

116. CW2 was a key account manager in Ireland from December 2016 to April 2020. CW2 was responsible for the Company’s product sales in Ireland, and reported to the country director for the UK and Ireland. For most of CW2’s tenure, CW2 reported to Chris Venn, but during CW2’s final year with the Company, CW2 reported to Mike Bee. The country directors, Venn and Bee, reported to chief commercial officer Hugues Sachot.

117. Corroborating CW1’s account, according to CW2, Kiran Bhirangi – Correvio’s former vice president of clinical development and medical affairs – was in charge of running the SPECTRUM study. CW2 believed Bhirangi joined the Company in “about 2015” and assumed responsibility of SPECTRUM after that. CW2 recalled that, “when I joined, Kiran was in charge. He was doing discussions with the FDA.”

118. CW2 recalled about the SPECTRUM study, “Obviously, it was a very important project for the Company. All senior management, whether their time was taken up talking to the FDA or preparing documents for the FDA,” were involved. CW2 noted that, in short, it was a “small company, and it was a major workstream and it seemed to take up a lot of their time.”

119. CW2 indicated that with respect to the Resubmitted NDA, Defendant Corrigan “would have been leading, and Sheila Grant would have been the medical affairs lead.” According to CW2, Defendant Grant “oversaw the regulatory side of things within the Company.”

120. CW2 noted that Correvio was a small company and everyone in the Company was aware that obtaining FDA approval of the Resubmitted NDA was an important project.

121. CW2 believed that there was potentially reliability bias in the SPECTRUM PASS study because there was bias in the registry. CW2 stated that bias resulted because the centers feeding into the study were centers that believed in the product and were well-equipped to use it. CW2 recalled that it was a small number of centers feeding into the study. The other element of SPECTRUM's bias was that it was skewed toward Northern Europeans, who CW2 stated may not reflect the U.S. population. CW2 noted that because any registry has bias, the FDA typically requires double blind trials.

122. CW3 was a key account manager in Spain from 2016 to September 2019. CW3 reported to the country director, Javier Carpintero, and was responsible for, among other things, Brinavess sales in Spain. Javier Carpintero reported to chief commercial officer Hugues Sachot.

123. CW3 was let go from Correvio a few weeks before the FDA rejected the Brinavess re-submission. CW3 recounted that the Company, "needed to re-adjust the team because the country director [Javier Carpintero] said we were going to stop selling cardiac products – that they lost the franchise for cardiac products."

124. CW3 learned of the FDA's rejection after leaving the Company. CW3 believed that the decision to stop promoting Brinavess in Spain was tied to the Company anticipating that the Resubmitted NDA would be rejected.

125. CW3 recalled that the Company held a global sales meeting – an annual meeting for the Company's entire sales force usually held in the beginning of the year (January or February) – in Greece in late January 2019 where *Defendant Corrigan rated the likelihood of*

the Resubmitted NDA's FDA approval as "50/50." CW3 remembered that Defendant Corrigan made this remark at dinner.

126. CW4 was a Country Director of UK and Ireland at the Company from January 2018 through April 2019. CW4 reported to the Company's chief commercial officer, Huges Sachot. CW4 ran a sales force of six individuals and loosely managed two UK-based medical representatives. CW4 was responsible for overseeing all sales and marketing activities in the UK and Ireland, including managing sales and budgets. Previously, CW4 was a Marketing Manager, Anti-Infectives, at the Company from January 2017 to January 2018.

127. CW4 was familiar with the Resubmitted NDA. CW4 recalled that as the re-submission progressed, CW4's team received regular updates from the U.S.

128. CW4 stated that executive leadership, including Individual Defendants Hunter, Grant and Corrigan, was "quite involved" in the resubmission application process. CW4 indicated that Defendant Grant "was quite heavily involved" and, in fact, "was running the process." CW4 also stated, "I know Mark Corrigan was quite involved and was moving into CEO because this was his thing – regulatory filings. It was something he'd done a lot in his Pfizer days."

129. CW4 corroborates CW3's account, and recalled that at CW4's final annual sales meeting at the end of January 2019 in Athens, Greece, Defendant Corrigan told the organization's global sales team that the Resubmitted NDA had *about 50-50 chance of getting approved*.

130. CW4 recalled that the meeting included country directors for the UK, France, Italy, Spain and Germany, and single key account managers from Finland and Belgium. CW4 recalled that all sales teams were there. In addition, CW4 noted that chief commercial officer

Hughes Sachot was there, as was Defendant Renz. Defendant Renz was present when Defendant Corrigan, stated to the global sales team that Brinavess had about a “50/50” chance of approval.

131. CW4 recalled that Brinavess posed serious risks and safety concerns. CW4 noted that there were a number of warnings and safety elements to the use of the drug. CW4 stated that *there was a restriction placed on the drug at the launch by UK authorities* – and they wanted a controlled launch – not going out to too many hospitals at once. CW4 recalled that Correvio employees had to go out to the hospitals and actually explain Brinavess’s risks. CW4 recalled that Brinavess changed the whole treatment paradigm from electrical cardioversion, so Correvio had to inform hospitals and medical professionals of Brinavess’s risks.

132. CW4 reported that, during CW4’s tenure at the Company, in addition to restrictions placed by regulatory authorities in Europe, *Correvio’s own leadership, including chief commercial officer, Hughes Sachot, “constantly told” its sales team to restrict promotions of Brinavess in the UK*. CW4 stated, “My boss [Hugues Sachot] was telling me not to push the drug very hard.” CW4 did not know why this was.

133. CW4 recalled that Correvio had an agreement with the Medicines & Healthcare products Regulatory Agency (“M.H.R.A.”) in the UK that limited Brinavess promotions. CW4 stated that Sachot limited CW4’s sale’s teams promotion of Brinavess even though the team was not promoting the drug up to the set limit. CW4 remembered an occasion when one of CW4’s sales employees wanted to attend a Brinavess meeting in New Jersey, which angered Sachot, and Sachot threatened to fire the employee. CW4 did not understand Sachot’s reaction, but surmised that Sachot “was concerned about us pushing Brinavess.”

134. CW5 was a regional key account manager/market access in Spain from November 2018 to February 2019. During CW5’s tenure with the Company, CW5 was responsible for

among other things, sales and market access of Brinavess in Spain. CW5 reported to Javier Carpintero, who reported to chief commercial officer Hugues Sachot. CW5 kept in contact with former colleagues that remained at the Company, who kept CW5 updated on what was happening within Correvio, including with Brinavess sales, after February 2019.

135. According to CW5, former colleagues told CW5 that around September 2019 they had been instructed to stop promoting Brinavess in Spain. This corroborates CW3's account, as well as CW4's account that the Company's chief commercial officer, Sachot, told sales representatives not to push Brinavess in the UK. CW5 found the decision to stop promoting to be "curious." At that time, according to CW5, Brinavess was selling very well.

136. CW5 recalled that during CW5's tenure with Correvio, the Company was marketing three products in Europe: Brinavess, Zevtera and Agrastat; Brinavess was number one. CW5 recounted that "after [September 2019], it was almost forgotten." CW5 believed the decision had been made by Hugues Sachot, Correvio's chief commercial officer. CW5 noted that the Company stopped paying commissions for Brinavess. CW5 didn't understand the Company's decision – CW5 opined that Brinavess was "the best product of the three."

137. CW6 was a Corporate Regulatory Lead, Senior Manager at Correvio from December 2011 to June 2014. During the Class Period, however, CW6 kept in close contact with a former colleague about the Brinavess resubmission. This colleague had responsibilities related to preparing the Resubmitted NDA, and CW6 provided advice to this colleague about the resubmission.

138. CW6 was familiar with the SPECTRUM study. With respect to the Resubmitted NDA, CW6 stated, "they really just went with SPECTRUM, and I know that for a fact. And the risk management plan. Their risk management plan was based on Europe."

139. CW6 recalled that Defendant Grant was “the one who pushed for that submission. They [Defendants] spent a lot of money on consulting companies and on getting the dossier submitted to the FDA.” CW6 opined that Defendant Grant “is the most influential person at Correvio today.”

140. CW6 recalled that Defendant Grant “was the one centralizing all the information. She would present to the board. She was very instrumental and passionate about Brinavess.” CW6 stated that there would also, “absolutely,” have been regular updates to the CEO (Corrigan). CW6 noted that “Mark [Defendant Corrigan] was really involved in the process of resubmission, from the beginning.” CW6 was informed by the former colleague, who had responsibilities for working on the resubmission, that Corrigan was present at all meetings discussing the Resubmitted NDA.

141. CW6 stated that during the Class Period, Company employees were shocked that Defendants pushed so hard for approval of the Resubmitted NDA knowing that there were other, safer, alternatives for AFib treatment. CW6 recalled that the former colleague confided in CW6 about the Resubmitted NDA, “[t]his is stupid. We’re throwing money at this, knowing there are alternatives.”

142. CW6 noted that the Company was “obsessed” with getting approval. CW6 recalled, “[t]he main objective was to get FDA approval. They tried to get share price up – to be able to invest in other products. Getting approval, for them, would raise the price of shares. Getting approval, for them, was like getting a golden ticket.” Toward this end, the Company “poured a lot of resources into getting it through.”

143. CW6 noted that after the Resubmitted NDA was not approved the Company did not appeal the FDA decision, suggesting that the Company could not provide data to contradict

the FDA's conclusions. CW6 surmised, "if they [Defendants] think the FDA's wrong, they should appeal the data. Why didn't they? If they believed that they should've appealed. Why didn't they have an oral explanation for the panel? For me, it's very bizarre. Nobody presented any further actions following the decision."

144. CW6 stated that Defendants kept the final draft of the Resubmitted NDA closely guarded. CW6 noted that "people usually share," so it was unusual that the Company kept the Resubmitted NDA confidential.

The Truth Begins to Unfold Through A Series of Partial, Yet Still Misleading, Disclosures

145. On December 6, 2019, the FDA released the Cardiovascular and Renal Drugs Advisory Committee briefing documents for the December 10, 2019 AdComm meeting.

146. The FDA Briefing Document contained a memorandum dated November 12, 2019 authored by Norman L. Stockbridge, MD, PhD, Director of Division of Cardiovascular and Renal Products. The memorandum was intended to provide the Cardiovascular and Renal Drugs Advisory Committee members with an overview of the December 10, 2019 meeting to discuss the Resubmitted NDA.

147. The briefing document concluded that Brinavess's "serious safety liabilities" were not outweighed by any benefits proffered by Brinavess:

Correvio has submitted an application to market Brinavess (vernakalant) for the rapid conversion of recent onset atrial fibrillation (AFib) to sinus rhythm (SR). Correvio has provided sufficient evidence of this benefit.

However, vernakalant has demonstrated serious safety liabilities (serious hypotension, ventricular arrhythmias, conduction abnormalities, death) in a target patient population (patients without heart failure (HF), hypotension, valvular disease) in which poor cardiovascular (CV) outcomes with either pharmacologic cardioversion (PCV) or electrical cardioversion (ECV) are not expected. Specific demographic and baseline disease characteristics that could prospectively exclude subjects who would experience these serious and

sometimes fatal adverse events after vernakalant administration have not been identified.

We do not believe that the benefit proffered by vernakalant, conversion of AFib to SR, outweighs the serious risks associated with its use.⁴³

148. In reaching this conclusion, the Cardiovascular and Renal Drugs Advisory Committee looked chiefly at three things: (1) the SPECTRUM PASS data; (2) the availability of safer alternatives and; (3) Correvio's proposed risk mitigation plan. The committee's analysis was conducted through the prism of the previously reported AEs and SAEs (especially the patient death) leading to the first NDA rejection and the dog studies (including the dog death).

149. The briefing document concluded the SPECTRUM data was unreliable and potentially inaccurate:

Our major concern is the potential selection bias related to the design and conduct of SPECTRUM which could significantly affect the validity of the study results. Evidence of selection bias in registries related to incomplete recruitment/inclusion (biasing toward a healthier group of patients) has been documented in the literature. Potential selection bias could be present in SPECTRUM as follows:

- The decision to treat with vernakalant IV was made by the physician independently of the study. Therefore, we do not know how physicians selected patients to receive vernakalant treatment in the study and whether the process was subject to bias. It is possible that a healthier group of patients or patients with certain characteristics were more likely to be selected for vernakalant injection. Compared to the clinical studies, a lower percentage of patients in SPECTRUM had a history of HF/structural heart disease.
- Enrollment was pursued after physicians had made the decision to treat patients. According to the applicant, to the extent possible, consecutive eligible patients were to be included. However, there are no objective data (e.g. hospital record search) to evaluate the degree and quality of the consecutive enrollment. Hence, we do not know whether all patients who were treated with vernakalant at a given site went through the screening/enrollment process. The fact that several sites had enrolled patients both prospectively and retrospectively suggests that not all treated patients were screened. In addition, because of the emergent setting potentially associated with administration of vernakalant, the timing of obtaining

⁴³ FDA Briefing Document, at 40.

informed consent varied on a case by case basis with some patients being treated before consent. It is possible that certain patients with serious outcomes after vernakalant treatment might not have been screened and enrolled.

- About 21% of screened patients were not enrolled in SPECTRUM. Ninety four percent of these patients refused to sign the informed consent. There was limited baseline information recorded (i.e., age and sex) for those who were screen failures. Hence, we do not know whether there are major differences regarding patient characteristics between those enrolled and not-enrolled.
- Because of the slow rate of recruitment, subjects could be enrolled retrospectively at all study sites in SPECTRUM. This change could introduce another layer of selection bias if retrospective selection of treated patients was somehow related to the outcome. In fact, patients had to survive and/or be in relatively good condition following vernakalant IV treatment in order to be approached by the study personal for enrollment. Retrospectively enrolled subjects could represent a healthier subset. We note that the percentage of patients with a history of HF was lower in retrospectively compared to prospectively enrolled subjects in SPECTRUM (0.9% vs. 3%).

Given that data collection in SPECTRUM relied on the availability of information in a subject's medical records, **there are also concerns regarding data accuracy and reliability. It is not clear whether SAEs were reported in a consistent manner in SPECTRUM**, particularly among retrospectively enrolled subjects. **The incidence of SAEs was three-fold higher in prospectively enrolled subjects compared to retrospectively enrolled subjects.** Retrospective patients were enrolled after the additional risk minimization measures (e.g., use of Pre-Infusion Checklist) were implemented in April, 2013. One could argue that the lower rate of SAEs among retrospectively enrolled subjects could reflect the effect of risk minimization measures. **However, this was not the case because the incidence of SAEs among prospectively enrolled subjects was similar regardless of the risk minimization activities (0.97% vs. 1.4% before and after April 01, 2013, respectively).** In addition, **the safety data from SPECTRUM are limited because useful information was not routinely collected (including BP and HR data during vernakalant administration).** Similar to what was observed in the clinical studies, approximately 4% of vernakalant-treated patients in SPECTRUM received only one dose of vernakalant but did not convert. In clinical studies, this subset of patients was at higher risk of experiencing larger decreases in BP, greater QT and QRS prolongation, and a higher incidence of AEs/SAEs. The majority of these subjects did not receive the second dose of vernakalant because they experienced an AE or SAE requiring acute ECV (~80%). However, based on the available narratives in SPECTRUM, **there was limited information regarding the reasons this 4% of subjects did not receive the second vernakalant dose. Approximately 70% of the subjects in this subgroup did not receive a second**

dose for “unknown” reasons. Hence, it is highly likely that AEs and possibly SAEs were underreported in SPECTRUM.⁴⁴

150. The Cardiovascular and Renal Drugs Advisory Committee also concluded that alternative therapies were safer than Brinavess treatment. The committee looked at ibutilide, an antiarrhythmic drug indicated for the rapid conversion of AFib of recent onset to SR, and electrical cardioversion (“ECV”), and concluded:

Our analysis did not identify an outcome of death in patients who would have been eligible for vernakalant treatment based on the exclusion criteria used in vernakalant’s randomized controlled trial, AFib Conversion Trial ACT-V. The few deaths among ECV literature reports or ibutilide PCV FAERS and literature reports occurred in patients who would not have been eligible to receive vernakalant in ACT-V, or based on limited data, it could not be determined whether a patient met eligibility criteria or deaths were related to ECV or ibutilide PCV.⁴⁵

151. Finally, the Cardiovascular and Renal Drugs Advisory Committee concluded that the proposed risk mitigation plan, REM, was not supported by sufficient evidence to conclude that the REM would sufficiently mitigate the risk of SAEs caused by Brinavess:

The applicant has proposed use of a “pre-infusion checklist” [] for health care providers to use prior to administration of vernakalant. The checklist is meant to highlight important contraindications (e.g., significant hypotension, LV dysfunction, conduction abnormalities) for treatment with vernakalant. **We believe there is insufficient evidence to suggest that exclusion of these groups will sufficiently mitigate the risk of SAEs caused by vernakalant.** Specifically, the patient who died in ACT V, leading to the clinical hold for the vernakalant IND, would not have been excluded by use of this checklist.⁴⁶

152. On this news, Correio’s stock price fell \$0.86 per share, or 39.81%, to close at \$1.30 per share on December 6, 2019.

⁴⁴ FDA Briefing Document, at 36-37.

⁴⁵ FDA Briefing Document, at 39.

⁴⁶ FDA Briefing Document, at 39.

153. Despite this partial revelation of the truth regarding the Resubmitted NDA, Defendants led the market to believe there was still hope for the Resubmitted NDA.

154. Analysts relied on and absorbed Defendants' reassurances. One analyst at Cantor Fitzgerald in a report dated December 6, 2019 noted that based on conversations with the Company, Defendants were sufficiently prepared to assuage the committee's concerns:

Today (12/6), the AdCom materials for CORV's Brinavess (vernakalant) became available. The briefing materials and draft questions were as expected, and focused on safety. The PDUFA date is 12/24, but given the timing of the AdCom as well as the upcoming holiday season, we think there is a chance the decision comes in very early 2020.

In short, *safety continues to remain a concern for the FDA, and they raise questions regarding the large SPECTRUM study which was supposed to address those concerns. We spoke with CORV this morning and the company is ready to address the FDA's questions head on.* We would note some inaccuracies in the FDA's briefing document which we think will be addressed at the meeting. *Despite the cautious tone of the materials, we still believe there is a large unmet need for a drug like Brinavess and we are hopeful the Agency can find a path to approval.*

155. On December 10, 2019, during pre-market hours, the NASDAQ suspended trading in Correio securities in anticipation of the Cardiovascular and Renal Drugs Advisory Committee's review and discussion of the Resubmitted NDA.

156. Just before market-close that day, the Cardiovascular and Renal Drugs Advisory Committee voted 11-2 against approval of the Resubmitted NDA, noting that Brinavess's benefit-risk profile was not adequate to support approval.

157. Correio announced the news that the committee jointly voted that the benefit-risk profile was not adequate to support approval (Vote: 2 Yes to 11 No):

The U.S. Food and Drug Administration (FDA) Cardiovascular and Renal Drugs Advisory Committee (CRDAC) met to review the Company's New Drug Application (NDA) seeking approval for Brinavess. The Committee jointly voted that *the benefit-risk profile was not adequate to support approval* (Vote: 2 Yes to 11 No). Brinavess is Correio's anti-arrhythmic drug that is currently under

review by the FDA for the rapid conversion of recent onset atrial fibrillation (AF) in adult patients. While the FDA is not required to follow the committee's vote, the agency considers the committee's recommendations when making its decision. Correvio's NDA seeking approval for Brinavess is under review by the FDA with a target action date of December 24, 2019 under the Prescription Drug User-Fee Act (PDUFA).

158. Following this news, and after Correvio shares resumed trading on the NASDAQ, the Company's stock price fell \$0.94 per share, or 67%, to close at \$0.46 per share on December 11, 2019, damaging investors.

159. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

FURTHER POST CLASS PERIOD REVELATIONS: FDA GIVES CORREVIO A CRL AND REQUIRES ADDITIONAL STUDIES TO SUPPORT RESUBMITTED NDA

160. On December 24, 2019, Correvio announced it had received a Complete Response Letter ("CRL") from the FDA regarding the Resubmitted NDA for Brinavess. The CRL stated that the FDA determined it could not approve the Brinavess NDA as submitted and provided recommendations needed for resubmission. The Company's 6-K advised:

In the CRL, the FDA stated that while the submitted data provides substantial evidence of Brinavess' effectiveness, **the data do not provide reassuring evidence of Brinavess' safety. The FDA indicated that Correvio will need to develop an approach to select patients who are at low risk of adverse cardiovascular reactions and that data from an additional, potentially uncontrolled, clinical study will be needed to assess Brinavess' cardiovascular risk in the selected patient population and to support an NDA resubmission. The FDA also stated that the risk of serious cardiovascular adverse reactions will need to be much less than 1% in the selected patient population.**

Correvio intends to request a meeting with the FDA as soon as possible to discuss the design and specifics of a potential study to address the FDA's concerns and currently believes that enrollment of both US and ex-US subjects may be acceptable to the Agency based on preliminary feedback. As previously announced, Correvio is also exploring strategic alternatives for the Company and/or its assets. Potential strategic alternatives that may be evaluated include, but

are not limited to, an acquisition, merger, business combination or other strategic transaction involving the Company or its assets.

161. Thus, after Defendants assured investors throughout the Class Period that no additional studies would be needed to support Brinavess's Resubmitted NDA because of the SPECTRUM safety data, Defendants revealed that—due to SPECTRUM's glaring deficiencies and problems, which were known to or recklessly disregarded by Defendants during the Class Period—Correio was in fact required to complete additional studies evaluating Brinavess's safety to support a resubmission.

DEFENDANTS' FALSE & MISLEADING CLASS PERIOD STATEMENTS

162. The Class Period begins on September 5, 2018, when Defendants issued a press release announcing preliminary results from the SPECTRUM study. According to the Company, there were zero deaths reported and safety outcomes of interest were observed in 0.8% of cases. Over 70% of AFib episodes were successfully converted to sinus rhythm in a median time to conversion of 11 minutes. Defendants touted the SPECTRUM study:

*This large European registry provides important data on the safety, efficacy and use of Brinavess in 1,778 patients in a real-world setting,” said Kiran Bhirangi, M.D., Correio’s Vice President, Clinical Development and Medical Affairs. “In SPECTRUM, normal heart rhythm was restored in over 70% of patients at a median time of 11 minutes, **HQIs were observed in 0.8% of patients, and there were no deaths.** SPECTRUM efficacy and safety results compare well with what has been observed from a literature review of 18 Brinavess studies from 20 centers in 9 different countries. Collectively, these studies reported on an additional 1,361 patients treated with Brinavess and demonstrated a median rate of cardioversion of approximately 74% (range 52.2% – 95%), a median time to cardioversion of 11.8 minutes (range 8-62 minutes), and there were no deaths reported. **We are encouraged by the consistency of the efficacy and safety data observed in the clinical setting** and we thank the SPECTRUM study investigators and the hospital site staff for their hard work and commitment to this valuable registry.*

163. The September 5, 2018 press release announcing the SPECTRUM study results was materially false and misleading because Defendants omitted and failed to disclose

significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvio to conduct additional studies to support a resubmitted NDA.

164. On October 23, 2018, Correvio issued a press release during pre-market hours announcing the Company's intention to move forward with the Resubmitted NDA. The October 23, 2018 press release stated in relevant part:

[B]ased on productive pre-NDA discussions with the U.S. Food and Drug Administration (FDA), Correvio plans to resubmit the Brinavess® (vernakalant hydrochloride, IV) New Drug Application (NDA) during the second quarter of 2019. Brinavess® is Correvio's antiarrhythmic drug for the rapid conversion of recent onset atrial fibrillation (AF). ***The FDA agreed that no additional studies would be required for the resubmission of the NDA.*** "These communications, including our recent pre-NDA meeting, represent a significant milestone for Correvio, since ***we have learned from the FDA that it would be permissible to resubmit the NDA with the clinical and post-marketing surveillance data that we have already collected,***" said William Hunter, MD, CEO and President of Correvio. "We are pleased with the collaborative nature of the FDA discussions that clarified a path forward for resubmission of the Brinavess NDA in Q2 2019, and we look forward to working closely with the FDA during the review process." Brinavess has active marketing authorization in 40 countries outside the U.S. and has accumulated eight years of post-marketing data.

165. The October 23, 2018 press release was materially false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material

deficiencies were so severe as to require Correvio to conduct additional studies to support a resubmitted NDA.

166. On November 6, 2018, Defendants held an earnings call to discuss Q3 2018 financial results. During the call, Defendant Hunter touted the European SPECTRUM study and assured investors that the Resubmitted NDA did not need additional studies:

I'd like to bring your attention to five really highly significant developments. Perhaps most noteworthy, two weeks ago we announced that based on productive pre-NDA discussions with the U.S. Food and Drug Administration, Correvio plans to resubmit the Brinavess new drug application during the second quarter of 2019.

We also reported positive preliminary data from the SPECTRUM study, a post-marketing authorization safety study conducted in the EU evaluating Brinavess over 2,000 treatment episodes of atrial fibrillation, which I will go into in more detail later.

...

Moving on to slide four, as previously mentioned, following our discussions with the FDA in October, we intend to resubmit the Brinavess NDA during the second quarter of 2019. As you know, Brinavess, or vernakalant, is an intravenous antiarrhythmic indicated for the rapid conversion of recent onset atrial fibrillation in patients without significant heart failure. ***Importantly, the FDA did not request any additional studies in order to resubmit our NDA.*** We expect that the regulatory review period for Brinavess will be approximately six months, so it is possible that we could receive an FDA approval decision during the fourth quarter of 2019.

I'd also like to highlight that in support of our NDA application, we are now in a position to share with the FDA over eight years of real-world experience from approximately 40,000 patients treated across the 40 different countries where Brinavess has active market authorization. ***Preliminary post-marketing surveillance data from the SPECTRUM study was made available to the FDA as part of our pre-NDA discussions.***

...

Turning to the next slide, we recently announced our preliminary data from the SPECTRUM study.

...

With respect to safety results, a total of 19 health outcomes of interest, defined as significant hypotension, ventricular arrhythmia, atrial flutter or bradycardia were reported in a total of 17 patients. 28 serious adverse events were reported for 26 patients, and no deaths were reported in the study.

...

The safety data showed no deaths and a 0.8% rate of significant side effects. Efficacy was excellent. Over 70% of AF patients were successfully converted in a median time of just 11 minutes. When you combine SPECTRUM with other real-world Brinavess success, it has allowed us to reengage with the FDA and outline a path forward that could and probably should lead to resubmission of our NDA in the second quarter of 2019. So thus far, 2018 has been probably the most eventful and positive year for the company since we evolved into a commercial organization approximately five years ago.

167. The foregoing statements about SPECTRUM results and the “path” forward toward regulatory approval were materially false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvio to conduct additional studies to support a resubmitted NDA.

168. After Defendants’ presentation, analysts drilled down on the progress for the resubmission, to which Defendant Grant touted the data Defendants had in 2018 to include in the resubmission and assured investors the only remaining steps to NDA submission was integrating that data:

ANALYST: Can you walk through any remaining steps that you might have before you file the NDA in the second quarter of 2019?

...

DEFENDANT GRANT: So the purpose of the pre-NDA meeting, as you might expect, *was actually to go over the data that we have in our hands as of October 2018 vis-a-vis the data that was in the NDA submission in December 2006.* So from an FDA communications perspective, there's nothing specifically we need to communicate with them about up until the filing in second quarter of next year. *It is more take the feedback we got at the pre-NDA meeting, including the how we integrate the clinical data, what specific analyses are required, what studies are included and which are not included, and work towards a submission on target for the second quarter.*

169. The foregoing statements about the “remaining steps” to be taken before filing the NDA were false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvo to conduct additional studies to support a resubmitted NDA. Moreover, Defendant Grant omitted additional material facts necessary to make the statement not misleading, namely that the Resubmitted NDA had to be supported not only by sufficient safety data, but also by an adequate risk mitigation plan (“REM”) to mitigate risks caused by Brinavess. Defendant Grant made no mention of the required REM in her statement discussing “remaining steps,” or that developing an adequate REM was exceedingly problematic because Brinavess’s mechanism was unknown to Correvo.

170. On November 27, 2018, Defendants presented at the Piper Jaffray Healthcare Conference. During the conference, Defendant Hunter told investors the Company was “on track towards submitting an NDA” that was “based on extremely impressive data” that came

from SPECTRUM, which showed a “really nice safety profile.” Defendant Hunter stated in relevant part:

So over the last little while we’ve had a number of really important events and I think to be quite honest with you the last six or seven months have probably been the most active in the company’s history.

We had some interesting news from the US FDA with respect to Brinavess, a drug that had and has been on clinical hold for a number of years in the US and *we are now on track towards submitting an NDA for the product in second quarter of the year*, which I’ll come back to. *That was based on extremely, an impressive data that came of a 2,000 patient study in Europe called Spectrum, which showed a really nice safety profile and a nice efficacy profile as well.*

Brinavess as I mentioned, we had a Type A meeting in June that allowed us to go forward with a pre-NDA meeting, which was scheduled for October. That meeting happened in October. And during that meeting we’ve got to go ahead to submit our NDA, *that the data that we were in possession of would satisfy the needs for the NDA to be reviewed.*

Importantly, there were no additional studies that needed to be done, either of the clinical or record review nature, we had what we needed to do. That sets us up to file our NDA in the second quarter of 2019, because this is a re-filing, it should be a six-month review and meaning that we should have an answer from the agency prior to the end of 2019 with the potential to actually launch this product in the beginning of 2020.

We also have been doing work on the intellectual property position on this drug and believe that we will have a patent extension through 2031. So with a launch in 2020 and 2031 patent date, *we feel the product has a wonderful opportunity in front of it in the United States. Spectrum really set this up for us.* We had a 2,000 dose study, which was on 1,800 patients approximately 1,800 patients. Some of the patients were treated more than once. And we found that and we had a 70 plus percent efficacy rate for the drug, which is actually better than the clinical trials in Phase 3 that led to the approval of the drug in Europe. And that probably has to do a little bit with refining the patients that we give the drug to and using the drug for really acute onset first 48 hours first or second time presentation of AFib. *But importantly, we had no real safety issues whatsoever. We had no deaths reported in that study.*

And importantly if you look at the health outcomes of interest so cardiovascular effects were less than 1%, that is highly comparable and arguably better than what’s seen with a lot of other treatments out there.

171. The foregoing statements about the preparation of the NDA and the SPECTRUM data, including that it was “extremely [] impressive” and posed “no real safety issues”, were materially false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvo to conduct additional studies to support a resubmitted NDA.

172. On March 13, 2019, Correvo filed an Annual Report on Form 40-F with the SEC, signed by Defendant Hunter, reporting the Company’s financial and operating results for the quarter and year ended December 31, 2018 (the “2018 40-F”). In it, Defendants touted the Company’s 2,000-patient PASS conducted in the European Union “to characterize the normal use and dosing of the product, and to provide better estimates of the incidence of medically significant health outcomes of interest.” Specifically, the AIF touted that “[z]ero deaths were reported and safety outcomes of interest were observed in 0.8% (95% confidence interval: 0.5% - 1.4%) of cases.”

173. The foregoing announced SPECTRUM study results were materially false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the

foregoing material deficiencies were so severe as to require Correvio to conduct additional studies to support a resubmitted NDA.

174. Also on March 13, 2019, Correvio issued a press release announcing the Company's Q4 2018 and FY 2018 results. The March 13, 2019 press release stated, in relevant part:

“By all accounts, 2018 was a pivotal year for Correvio, marked most importantly by the advancement of our discussions with the U.S. Food and Drug Administration (FDA) and their decision to permit our resubmission of the New Drug Application (NDA) seeking approval for Brinavess™ as a new treatment for the rapid conversion of recent onset atrial fibrillation (AF) in adult patients,” said William Hunter, MD, CEO of Correvio. “We remain on track to resubmit the NDA during the second quarter of 2019. On the commercial front, we continue to generate strong sales momentum and achieved record revenues of \$28.7 million, a 20% increase over the prior year.”

Correvio announced that, ***based on productive pre-NDA discussions with the U.S. FDA, it intends to resubmit the Brinavess NDA during the second quarter of 2019. The FDA agreed that no additional studies would be required for the resubmission of the Brinavess NDA.***

175. The March 13, 2019 press release was materially false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvio to conduct additional studies to support a resubmitted NDA.

176. On March 13, 2019, the Company held its Q4 2018 earnings call. On the earnings call, Defendants touted the SPECTRUM data and noted that the most important thing for the

Company was the Resubmitted NDA. Defendant Hunter lauded the SPECTRUM data, including the safety outcomes:

Following productive pre-NDA discussions with the U.S. Food and Drug Administration, we plan to resubmit the Brinavess New Drug Application during the second quarter of 2019. ***The FDA's decision to allow this resubmission was partially driven by the positive data generated from SPECTRUM, a post-authorization safety study conducted in the EU evaluating Brinavess in over 2,000 treatment episodes of atrial fibrillation, which I will go into more detail about in a few minutes.***

...

As previously mentioned, following our discussions with the FDA in October, we intend to resubmit the Brinavess NDA during the second quarter of 2019.

As you know, Brinavess or vernakalant is an intravenous antiarrhythmic indicated for the rapid conversion of recent onset atrial fibrillation in patients without significant heart failure. ***Importantly, the FDA did not request any additional studies in order to resubmit the NDA.*** We expect that the regulatory review period for Brinavess will be approximately 6 months. So it's possible we could receive an FDA approval decision during the fourth quarter of 2019.

I'd also like to highlight that in support of our NDA application, ***we are now in a position to share with the FDA over 8 years of real-world experience from the aforementioned 55,000 treated patients. Preliminary post-marketing surveillance data from the SPECTRUM study was made available to the FDA as part of our pre-NDA discussions.***

...

The drug, of course, has this long clinical history. It's been used in multiple countries, and I think that's really important because there are differences in the practice of medicine around the world, and despite the fact that this is used by different people in many different parts of the world, the drug continues to have very high efficacy rates, routinely over 70%, sometimes higher. And the drug just doesn't seem to show any safety signal whatsoever, meaning that not only is -- it seems to be very effective, but we and others are successful in marketing this drug in a way that seems to make it really quite safe and quite consistent with what we've seen in the SPECTRUM data. I believe this will open up an incredible opportunity for the company one way or another as to how we manage the product going forward.

...

We have a summary of the preliminary data from the SPECTRUM study
With respect to safety results, the cumulative incidence of health outcomes of interest defined as the – as significant hypotension, ventricular arrhythmia, atrial flutter or bradycardia were reported in only 0.8% of patients. 28 serious adverse events were reported for 26 patients, and no deaths were reported in the study.

. . . .

Looking forward, the most important thing this company will do is file that NDA, have that NDA accepted and ideally move on to approval before the end of the year.

. . . .

Unfortunately, we had a broken asset, and we had just been given that back from a corporate partner. The only thing we could do because we were on clinical hold, meaning that we could not do clinical studies in the United States, is the only thing we could do is complete the SPECTRUM study that we had in Europe, which was a postmarketing surveillance study. One can't do a post-marketing surveillance study without marketing entirely a new drug. So from scratch, we built an entire sales force in Europe. We did a number of transactions to keep the share count low and to finance this business in the least dilutive way possible. I'm -- I alluded already to the Aggrastat transaction, but the Cipher transaction was another one of those. CRG has stepped up in a huge way to help us finance this turnaround. All of those were non-dilutive financings that amount to, I don't know, Justin, \$230 million, \$240 million, somewhere around there? Yes. ***And so that has allowed us to get a huge study done in Europe that was very, very positive. The SPECTRUM study is a really nice study.*** We got efficacy results that were better than could have been anticipated from the Phase III studies. ***There was no safety signal in that.*** There has been no safety signal in 14 or 15 other publications that have been put together that are another 1,400 patients, and there has been no safety signal in 55,000 people treated in multiple countries around the world. So that plan all came together.

. . . .

So the execution, I think, has been really incredible. Things don't always happen on the time line that you expect, but I think, really, the business plan has come together in a great way. And I couldn't feel better about the fact that Mark is taking over to shepherd ***the most important next step in the business, which, of course, is the filing and acceptance, and hopefully, approval of that NDA.***

177. Analysts questioned Defendant Hunter about the future of Brinavess, to which Hunter claimed that SPECTRUM had “derisked” Brinavess’s regulatory pathway and created immense value for shareholders in 2019:

ANALYST: First, I wanted to reiterate, I guess, what many have said and what you said, Bill, that they -- you guys came into a tough situation and really creatively financed it without much dilution and put the shareholders in a position to have a nice reward before too long here, thanks for that. I guess, is there anything you can tell us, give us some sense of how discussions are going with potential partners for Brinavess at this point?

DEFENDANT HUNTER: . . . So if you just look at the minuted history of the drug, it goes back many, many years as you can probably appreciate. And it’s got a lot of history and nuance and elements to it. And so that’s probably the biggest issue. It’s probably the reason our stock isn’t a lot higher than it is or probably should be, quite frankly. And – so that’s it. *And I believe as we continue to derisk the regulatory pathway and last year was a huge step in doing that. I mean, SPECTRUM getting us to the NDA, the pre-NDA meeting getting to go ahead to file the NDA, that was, I think created immense value. And I think once that NDA is filed, I think once that NDA is accepted, and now you’re into final stretch of review, that will derisk the asset an awful lot. So that’s where we’re focused on. That’s where, I think, the money is in 2019.*

178. Defendants’ statements in ¶¶ 176-77 were false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correivio to conduct additional studies to support a resubmitted NDA. Moreover, Defendant Hunter’s statement knowingly or extremely recklessly misrepresented Brinavess’s prospects for FDA approval; while Defendants claimed that they had “derisked” the regulatory pathway because the NDA was accepted for review, Defendant

Corrigan internally acknowledged in January 2019 that the Resubmitted NDA only had about a 50/50 chance of approval.

179. On May 8, 2019, Defendants held an earnings call to discuss Correvio's Q1 2019 results. Defendant Corrigan continued to reassure investors that Brinavess's NDA was on track and supported by the SPECTRUM safety data. Defendant Corrigan stated:

Following positive discussions with the FDA in October of 2018, we remain on track to resubmit the Brinavess NDA during the second quarter of 2019. As you know, Brinavess, or vernakalant, is an intravenous antiarrhythmic medicine indicated for the rapid conversion of recent onset atrial fibrillation in patients without significant heart failure. ***Importantly, the FDA did not request any additional clinical studies nor to resubmit the NDA.*** We expect the regulatory review period for Brinavess will be 6 months, though it's possible we could receive a decision from the FDA in the fourth quarter of 2019.

I'd also like to highlight that in support of our NDA application, we are now in a position to share with the FDA over 8 [worlds] of real-world experience from approximately 55,000 treated patients, plus data from the post-approval SPECTRUM study.

...

The recent advancement towards a resubmission of the Brinavess NDA has also opened up the potential for strategic transaction around this asset.

We have a summary of the data from the SPECTRUM study.

...

With respect to safety, the cumulative incidents of health outcomes interest, defined as significant hypertension, ventricular arrhythmia, atrial flutter or bradycardia, were reported in less than 1% of patients. 28 serious adverse events reported for 26 patients and no deaths reported in the study.

180. Analysts attempted to drill down on the progress of the resubmission to which Defendant Corrigan assured investors that the NDA was supported by excellent safety data.

ANALYST: Mark and Justin, I just have quick questions for me. Regarding Brinavess, I know you stated that you are planning to submit it this quarter. Is -- ***what's left in trying to get done before submitting it? Is it just the administrative stuff?*** And based on your conversations previously now going into this

resubmission, do you have a feel for whether it's going to be a real 6- month review or it could be even less than that?

DEFENDANT CORRIGAN: That's the question we're talking about that yesterday. You must have ears on the walls here. Let me take the first one. *In the pre-NDA meeting, we discussed with the FDA what the data groupings they'd like to see. And they prompted the inclusion of 2 studies that weren't in the original file. So part of that has been the inclusion of those 2 studies.* And secondly, the -- this is really about the writing and integrating data process. So this is pretty standard NDA assembly, I would say, and time lines, which, of course, then there's allowable period for publishing. So it's -- *when I look at it, what's different about it fundamentally is really bringing forward real-world experience. If you think about it, in addition to the clinical trials, which would - - were part of the original NDA, we're adding 3 major data sets to this, okay? SPECTRUM study, number one. Number two, there have been 2,000 patients treated in really several states, more than 20 studies by investigator-initiated studies, which provide a pretty interesting data set. While not all combinable, but certainly under clinical research conditions that vary from randomized clinical trials to observational studies, but provides another 2,000 patients in the study condition that, I think, are relevant.* And then lastly, the periodic safety update reports on the 55,000 patients treated is an important third element. So those are *the 3 major data elements that speak to the safety and efficacy profile in real-world that have to be integrated to the NDA.* Turning now to your second question. I have -- I don't think it will be less than 6 months. While they certainly have seen that first part of the NDA, I think they're going to consider carefully the rest. And in general, the FDA is pretty overburdened. And so I think they will look at this very carefully. That's what we've asked them to do. And I think that I would be pleasantly surprised with an earlier decision, but that's not what we're counting on.

181. Defendants' statements in ¶¶ 179-80 were materially false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correio to conduct additional studies to support a resubmitted NDA. In addition, Defendant Corrigan omitted additional

material facts necessary to make the statement not misleading, namely that the Resubmitted NDA had to be supported not only by sufficient safety data, but also by an adequate risk mitigation plan (“REM”) to mitigate risks caused by Brinavess. Defendant Corrigan made no mention of the required REM in the statement discussing “remaining steps,” and did not disclose that developing an adequate REM in fact was extremely problematic because Brinavess’s mechanism was unknown to Correvio.

182. On June 24, 2019, Correvio issued a press release announcing its resubmission of the Brinavess NDA for the treatment of patients with recent onset AFib to the FDA (the “June 2019 Press Release”). That June 24, 2019 press release cited a purportedly overwhelming body of evidence on Brinavess’s safety profile that supported the Resubmitted NDA, touting that “[t]he NDA is supported by data from SPECTRUM, a post-approval safety study . . . which evaluated 1,778 unique patients across a total of 2,009 treatment episodes following administration of Brinavess,” of which ***“[t]he cumulative incidence of health outcomes of interest (defined as significant hypotension, ventricular arrhythmia, atrial flutter, or bradycardia) were reported in 0.8% of patients”; “[t]wenty-eight serious adverse events were reported in 26 of the 1,778 patients and no deaths were reported in the study”;*** and that “[i]n addition to SPECTRUM, the Brinavess NDA is also supported by nine Phase 3 and Phase 2 clinical trials and over eight years of real-world experience in approximately 50,000 treatment patients worldwide.”

183. The June 24, 2019 press release also quoted Defendant Corrigan, who asserted that “[t]he resubmission of the Brinavess NDA is a major milestone for Correvio and is the culmination of substantial effort by our employees and the investigators who have dedicated themselves toward investigating this potential new treatment option for adult patients with recent

onset AF.” Defendant Corrigan also touted that, “[i]f approved, [Defendants] believe that Brinavess will be an attractive addition to the AF treatment landscape and will provide physicians with a well tolerated and effective pharmacologic treatment approach to cardioversion.” Finally, Corrigan cited the “the FDA’s willingness to work with [Defendants] during the resubmission process” and assured investors that Defendants “look forward to working closely with the FDA as they review *the new data supporting the safety and efficacy of Brinavess.*”

184. The June 24, 2019 press release was false and misleading because the new data did not support the safety of Brinavess and Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correio to conduct additional studies to support a resubmitted NDA.

185. On July 25, 2019, Correio issued a press release announcing the FDA’s acceptance of the Resubmitted NDA, an assigned target action date of December 24, 2019, and the FDA’s plan to hold an advisory committee meeting to discuss the Resubmitted NDA. That July 25, 2019 press release contained substantively identical statements to those contained in the June 24, 2019 press release concerning the body of evidence supporting Brinavess’s safety profile and the Resubmitted NDA. The July 25, 2019 press release also quoted Defendant Corrigan, who asserted that “[t]he FDA’s acceptance of this resubmitted NDA marks another important milestone for Correio and for the global Brinavess program,” and that, “[a]s a

potential new AF treatment, with a well-characterized efficacy and safety profile, [Defendants] believe that Brinavess, if approved, will be an attractive addition to the AF treatment landscape.” The July 25, 2019 press release went on to tout the SPECTRUM safety data:

*The Brinavess NDA is supported by data from SPECTRUM, a post-authorization safety study that was conducted in Europe which evaluated 1,778 unique patients across a total of 2,009 treatment episodes following administration of Brinavess. The SPECTRUM data demonstrated that treatment with Brinavess successfully converted 70.2% of those treated AF patients into normal sinus rhythm. In addition, treatment with Brinavess showed a median time to conversion of 11 minutes from the start of the first infusion among patients who successfully converted. **The cumulative incidence of health outcomes of interest (defined as significant hypotension, ventricular arrhythmia, atrial flutter, or bradycardia) was reported in 0.8% of patients. Twenty-eight serious adverse events were reported in 26 of the 1,778 patients and no deaths were reported in the study.***

186. The July 25, 2019 press release was false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correio to conduct additional studies to support a resubmitted NDA.

187. On August 14, 2019, Correio issued a press release announcing the Company’s Q2 2019 financial results. In the August 14, 2019 press release, Defendants touted the “top-line” data from SPECTRUM supporting the Resubmitted NDA:

The U.S. FDA accepted for filing Correio’s resubmitted NDA seeking approval for Brinavess for the rapid conversion of adult patients with recent onset AF. The FDA assigned a target action date of December 24, 2019 under the Prescription Drug User Fee Act (PDUFA).

- An abstract highlighting the results of the SPECTRUM study was selected for a poster presentation at the upcoming European Society of Cardiology (ESC) 2019 Congress taking place August 31 – September 4, 2019, in Paris. ***The Brinavess NDA is supported by data from SPECTRUM***, which is a post-approval safety study that was conducted in Europe and evaluated 1,778 unique patients across a total of 2,009 treatment episodes following administration of Brinavess. ***In the previously reported top-line data from SPECTRUM***, it was demonstrated that treatment with Brinavess successfully converted 70.2% (95% confidence interval; 68.1 – 72.2) of all treated patients.

188. The August 14, 2019 press release was false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correio to conduct additional studies to support a resubmitted NDA.

189. On August 14, 2019, Defendants held an earnings call to discuss financial results for Q2 2019. During the call, Defendant Corrigan touted SPECTRUM's safety data:

Following possible discussions with the FDA in October 2018, we submitted that Brinavess NDA during the second quarter of 2019. The NDA was accepted by the FDA in late July, and a target action date under the PDUFA act was assigned for December 24, 2019. We expect the regulatory review period for Brinavess will be 6 months, so it is possible we could receive a decision from the FDA during the fourth quarter of 2019 following a likely advisory committee hearing.

...

The recent advancement of Brinavess into the NDA phase has also opened up the potential for a strategic transaction around this asset.

In addition to this regulatory progress, on Slide 5, we have an overview of some other important Brinavess highlights. ***In late 2018, we reported top line results from the SPECTRUM study.*** SPECTRUM was conducted as part of follow-up measures agreed to for the European Medicines Agency in 2010.

In this perspective and retrospective observational registry, 1,778 unique patients, receiving a total of 2,009 treatment episodes, were enrolled to evaluate and obtain data on patients-administered Brinavess. That data for SPECTRUM was provided by 53 participating hospitals in the EU and demonstrated that treatment with Brinavess successfully converted 70.2% of all atrial fibrillation patients into normal sinus rhythm.

...

With respect to the safety results, a cumulative incidence of health outcomes of interest to find a significant hypotension, ventricular arrhythmia, atrial flutter or bradycardia were reported in less than 1% of patients. 28 serious adverse events were reported for 26 patients and no deaths reported in the study.

190. During the call, analysts drilled down on how the SPECTRUM data would support Brinavess's NDA approval and whether the data would impact the AdComm. In response, Defendant Corrigan misleadingly hyped SPECTRUM's support of Brinavess's safety profile:

ANALYST: Okay. And regarding the data that -- ***the SPECTRUM data*** that we are expecting at ESC in Paris, ***how would this help us investors to think about both ad com and also approval of Brinavess?***

DEFENDANT CORRIGAN: Yes, RK, it's a great question. So we actually think -- the FDA has ***seen a summary level of SPECTRUM data. In fact, it was the basis for our successful appeal to the FDA to allow us to submit the -- resubmit the NDA.*** So they've seen it in abstract form.

Obviously, what we have submitted to them are the full data sets. And so, again, the way I think about it is that ***we are standing on 3 pillars with regards to characterization of the safety of Brinavess for the U.S., which is the key point we have to make with them.*** And they are SPECTRUM, the investigator-initiated studies, and then the overall exposure to 55,000 database.

So it's part of our entire argument to the FDA with regard to really now that the drug has been out in clinical usage. And we think it has value as an observational study because it not only speaks to the safety of the product, it also speaks to the physician's familiarity with how to use it safely in a real-world situation, which is different, obviously, from a randomized, controlled clinical trial.

191. Analysts further attempted to determine the likelihood the AdComm would be positive based on the Resubmitted NDA's additional data. Defendant Corrigan dodged the question, speculating only as to the FDA's reasoning for holding another AdComm:

ANALYST: Yes. So Brinavess vernakalant went through an ad com years ago, and the vote was 6:2 in favor of approving the drug. And I think the 2 dissenters said that they wanted more data. *Now you've got that more data. I'm just wondering, in all likelihood, the ad com will come out positive. The last time the FDA voted -- or the FDA acted against the ad com recommendation, like why do you think the FDA wants an ad com again since they had a positive one the first time around?*

DEFENDANT CORRIGAN: That's an excellent one. If you think about it administratively, we remain on clinical hold, and which means that the FDA doesn't believe it's safe to be studied in those conditions. And that's a long way from that to an approval for widespread public use, and I think that they -- again, so I think this is a -- it's a prudent step by the FDA to ensure, I believe, that the field truly wants the drug. *And now, in light of this new data, they can like listen to the field, express their views and, at that point, lift the clinical hold and move on the process towards approval. I do think that if we were not on clinical hold that they may not have required the ad com.*

192. Defendants' statements in ¶¶ 189-91 were false and misleading because the Brinavess NDA was not adequately supported by the top-line data from SPECTRUM, and Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Corveio to conduct additional studies to support a resubmitted NDA. Moreover, Defendant Corrigan's statement knowingly or extremely recklessly misrepresented Brinavess's prospects for FDA approval; while Defendants claimed

the FDA could “move on the process of approval,” Defendant Corrigan internally acknowledged in January 2019 that the Resubmitted NDA only had about a 50/50 chance of approval.

193. On September 3, 2019, Correvio issued a press release announcing a presentation of Brinavess SPECTRUM data at the European Society of Cardiology 2019 Congress. That September 3, 2019 press release touted that the SPECTRUM trial supporting the Resubmitted NDA as a “prospective and retrospective, international, multicenter, observational registry, [where] 1,778 unique patients with 2,009 treatment episodes were enrolled to describe patients receiving Brinavess and to characterize normal conditions of use and dosing, and quantify possible medically significant risks associated with the use of Brinavess in real-world clinical practice.” It also touted that “*[i]n the safety results, a total of 19 health outcomes of interest (‘HOIs’, defined as significant hypotension, significant ventricular arrhythmia, atrial flutter with 1:1 conduction, or significant bradycardia) were reported in 17 of the 1778 patients enrolled (<1%)*”; that “*[t]he cumulative incidence of HOIs at study completion was 0.8% (95% CI: 0.5%-1.4%)*”; and that only “*[t]wenty-eight serious adverse events (SAEs, including the 19 HOIs) were reported for 26 patients,*” with “*no cases of torsades de pointes, ventricular fibrillation or deaths . . . reported in the study,*” thereby further assuring investors of Brinavess’s safety profile.

194. The September 3, 2019 press release reporting SPECTRUM results was false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM’s data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the

foregoing material deficiencies were so severe as to require Correio to conduct additional studies to support a resubmitted NDA.

195. On September 10, 2019, Defendants presented at the Rodman & Renshaw 21st Annual Healthcare Conference. During the conference, Defendant Renz praised the SPECTRUM safety data:

And the real most important study that we've just completed last year and that's the full results last week at the European Society of Cardiology is the results of the SPECTRUM study. For the SPECTRUM study, it was post authorization safety study in the EU. We did it in 6 countries, 53 centers, 1,778 patients or call it a couple of hundred as you might imagine were frequent flyers, they came back, with 2009 treatment episodes.

Efficacy was greater than 70%, 70.2% in the medium time to conversion of 12 minutes. This is really effective and really efficient in fact in our Phase 3s, the back in the late, our efficacy rate was in the mid 50% range.

So, in the real world, our drug has held up and actually had better efficacy in patients throughout Western Europe. *The SPECTRUM key safety observations are very important.* So in all of these treatment episodes is again in over 2,000 patients with a cumulative incidence of less than 1%. So, what did that mean, that means significant hypertension bradycardia, which is like a slow heart rate other arrhythmias very limited.

As you might imagine 28 FEs in 26 patients out of 2,000 for people who have cardiovascular challenges. *This is a very good outcome, this is a very, very, we believe safe drug.* You're not around the eyes and they claims of safety, but they want to point out compared to the other pharmacological treatment options, our drug compares favorably, for example, we have not had any torsades de pointes rather unusual ventricular arrhythmias, which is very helpful.

In the SPECTRUM study most importantly, perhaps was there were no deaths and as you might imagine these patients they have other comorbidities. So this was a very strong body of evidence in real world data. It's this real world body of data that the FDA gave us permission to refile upon, so we met with the agency last year to discuss our portfolio and they agreed to have a pre-NDA meeting with this last fall. We met with them last fall and they gave us the criteria of what they wanted to see in our submission. So, our team works very hard and submitted in the second quarter of this year following its head see meeting with full resubmission to Brinavess NDA.

The FDA accepted our file in late July this year, and gave us a PDUFA date of December of this year. We expect to have an advisory committee meeting sometime between mid-November and mid-December. It's not been published yet, but it's likely to happen in the later part of Q4.

196. Defendants' statements were false and misleading because SPECTRUM's "key safety observations" were unreliable, and SPECTRUM's outcome was not as rosy as Defendant Renz painted it, as Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvo to conduct additional studies to support a resubmitted NDA.

197. On October 4, 2019, Defendants presented at the Cantor Global Healthcare Conference. During the conference analysts attempted to drill down on Brinavess's FDA regulatory history, and questioned Defendant Corrigan about what would be different this time around:

ANALYST: Okay. So what happened was the last addcom for Brinavess. Can you give us a little bit of a background there and how long ago was it? ***And why do you think things will be different this time around?***

DEFENDANT CORRIGAN: Sure. Well, first of all, I'd love some things to be the same this time around. Yes. Addcom did 6:2 in favor of the product ten years ago. And so it was -- I think the field that time really recognize the need for better pharmacologic converting agent had wanted it as ***I said the agency wanted more safety data, we have now got that***, I think the FDA will ask this advisory Committee. ***Is that safety data package that we now see the accumulated 56,000 patients treated in Europe the post-approval safety studies SPECTRUM that was published in presented at the European Society of Cardiology last month sufficient now to mitigate the concerns over the one debt if you see.***

ANALYST: Okay. *And what gives you confidence in the FDA approval this year? What other additional data we may get into a little bit more details of the study that make you think and any interactions the FDA that might make you feel more confident?*

DEFENDANT CORRIGAN: *Well, first of all, I think the very fact that they have accepted the file, very fact that they would consider the NDA is in and of itself them taking it quite seriously, so I think they have seen that there are an accumulation of data sources now that would put them in a position to say, yes, we can now we consider the application. So I feel good about that. I have felt pretty good about the interactions we've had with them in terms of the datasets they've asked for in advance of the advisory committee meeting.*

ANALYST: Okay. And what are the possible topics do you think the addcom could discuss and how are you preparing for the meeting?

DEFENDANT CORRIGAN: *Sure. I think it's going to come down to really the safety track record.* I think efficacy is agreed upon. The FDA made that clear even 10 years ago, the efficacy is very solidly 50% versus single-digits in the placebo controlled groups and actually even better in the real world experience up to 70% to 85%. So, I think efficacy is off the table.

I think it's really about safety here and about who have the appropriate patients that should be treated with vernakalant and I think we have learned and then parts been in usage and so physicians have learned, the Europeans have revised the label. We now understand this is not patients who have structural heart disease shouldn't take the drug. Patients who have congestive heart failure shouldn't have a drug. On the other hand, it's really applicable to a large number of patients who present with because Atrial Fibrillation.

198. Defendants' statements were false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correio to conduct additional studies to support a resubmitted NDA. Moreover, Defendant Corrigan's statement knowingly or extremely recklessly

misrepresented Brinavess's prospects for FDA approval; while Defendants claimed the SPECTRUM safety data put the FDA in a position to "say yes" to the Resubmitted NDA, Defendant Corrigan internally acknowledged in January 2019 that the Resubmitted NDA only had about a 50/50 chance of approval.

199. On November 14, 2019, Defendants held an earnings call to discuss Correvio's Q3 2019 financial results. During the call, Defendant Corrigan touted the "strong body" of clinical data, especially the data from SPECTRUM, supporting the Resubmitted NDA:

I'd like to discuss a few updates related to Brinavess or intravenous vernakalant, our antiarrhythmic drug for the rapid conversion of recent onset atrial fibrillation to normal sinus rhythm in patients without significant heart failure. As a reminder, Brinavess is currently approved in 41 countries and is marketed in over 30 countries, including most of Europe and Canada. Following positive discussions with the FDA in October 2018, we resubmitted the Brinavess NDA during the second quarter of 2019. The NDA was accepted by the FDA in late July and a target action date of December 24, 2019, was assigned under the PDUFA Act.

We also recently announced that FDA will hold the Cardiovascular and Renal Drugs Advisory Committee meeting in connection with its review of the pending Brinavess New Drug Application on December 10, 2019, from 8 a.m. to 5 p.m. Eastern Time.

...

The Brinavess NDA is supported by a large and strong body of both clinical data and real world experience. The largest data set is from the SPECTRUM study. SPECTRUM was conducted as part of the follow-up measures agreed to with the European Medicines Agency in 2010. In this perspective and retrospective observational registry, 1,778 unique patients receiving a total of 2,009 treatment episodes were enrolled to evaluate and obtain data on patients administered Brinavess. The data for SPECTRUM was provided by 53 participating hospitals in the EU and demonstrated that treatment with Brinavess successfully converted 70.2% of all AF patients into normal sinus rhythm. Treatment with Brinavess showed a median time of conversion of 12 minutes from the start of first infusion among patients who successfully converted, most of whom were successfully discharged from the emergency department.

With regard to the safety results, the cumulative incidence of health outcomes of interest, defined as significant hypertension, ventricular arrhythmia, atrial flutter or bradycardia were reported in less than 1% of patients. 28 serious

adverse events reported for 26 patients, and no deaths nor torsades des pointes were reported in the study.

Since its approval in Europe 8 years ago, numerous prestigious investigators and institutions have studied Brinavess in both investigator-sponsored and post-marketing approval studies across many countries in Europe, Scandinavia and South America, gathering extensive data about its real-world clinical settings. *As we await the FDA's decision on Brinavess, we can proudly say that to date, approximately 59,000 patients have been treated with Brinavess, not including patients treated in the SPECTRUM study.*

...

On Slide 6, we have an overview of the new SPECTRUM data being presented at AHA 2019 this weekend. Again, this was a subset of 1,289 patients who were specifically treated in the emergency department setting. In this analysis, Brinavess successfully converted 70.2% of all AF patients to normal sinus rhythm with a median time conversion of 12 minutes. The median length of hospital stay for these patients was 7.5 hours, and only 13% were in the hospital for greater than 24 hours. *For safety, there were 12 adverse events of special interest reported in 11 patients, a rate less than 1%. No serious adverse events resulted in sequelae, and there were no deaths and no reported cases of torsades des pointes.*

200. During the call, analysts attempted to drill down on Defendants' expectations related to the AdComm and how communications with the FDA were progressing as to the Resubmitted NDA. Defendant Corrigan dodged the question and focused only on the PDUFA date:

ANALYST: And going from China to the U.S., in terms of how the AdCom Panel has been set up for the December 10 and the PDUFA date just being 2 weeks from then, so what are the expectations there from the AdCom? How -- especially, would that somehow move the PDUFA date by any means? *I'm just trying to get a feel for like how your conversations are going with the FDA on the file itself*, independent of the AdCom recommendation.

DEFENDANT CORRIGAN: That's an excellent question, RK, and one that we discuss internally. I think this is really in the FDA's court. They've set up the dates. The dates are -- they have the opportunity to set the AdCom. It wouldn't be the first time that a PDUFA date has moved. I don't think that that's -- if we have a positive advisory committee and we are engaged with the FDA in discussions with regard to labeling, I will be very pleased and I will not despair over a slip in

that PDUFA date. It is a very short window for them to construct labeling. You're right on target with that.

201. Defendants' statements in ¶¶ 199-200 were false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correio to conduct additional studies to support a resubmitted NDA.

202. On November 18, 2019, Correio issued a press release announcing the presentation of new Brinavess SPECTRUM data at the American Heart Association 2019 Annual Meeting. That November 18 2019 press release touted that, *“[i]n the safety results, there were a total of 12 serious adverse events (SAEs) of special interest in 11 patients (0.9%; 95% CI 0.4-1.5%), the most common of which was significant bradycardia (n=9, 0.7%), one of which was associated with significant hypotension (0.1%),” and “two 1:1 atrial flutter (0.2%), one of which was originally differentially evaluated as sustained ventricular tachycardia”; and that “[n]o serious Brinavess- related [adverse events] resulted in clinical sequelae and no deaths nor cases of torsades de pointes were reported in the study.”*

203. The November 18, 2019 press release reiterating the SPECTRUM results was false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required

information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvo to conduct additional studies to support a resubmitted NDA.

204. On December 3, 2019, Defendants presented at the Piper Jaffray 31st Annual Healthcare Conference. At the conference, Defendant Corrigan praised the SPECTRUM safety data underlying the Resubmitted NDA:

What was the body of evidence that allow the FDA to consider? Take the NDA as well as resubmitted. But was really led by SPECTRUM, SPECTRUM was the post approval safety study that was insisted upon by EMEA [ph] as a condition of approval. It consisted of 1,778 patients studying. This is a real world situation. These are patients who experience acute-onset atrial fibrillation, palpitations, sweatiness, comfortable, anxiety. They go to the emergency room. They're diagnosed with atrial fibrillation. And the healthcare provider in several countries in Europe in which this was studied made a decision that they may be eligible for pharmacologic conversion, that is an intravenous medicine that's applied, it expected within our median time 10 minutes of correcting the arrhythmia.

The other option, of course, is to stop [ph] the patient is to give them anaesthesia, possibly make [ph] them to hospital, anticoagulation possibly, and then apply paddles to try and correct the arrhythmia. In this IV Administration, in SPECTRUM, we saw efficacy at 70% within that 12 minute median time. *But the crucial aspect of SPECTRUM wasn't the efficacy, which was actually better than we have seen in the pivotals. It was that we had zero deaths in those patients. We had health outcomes of interest. In other words, the safety concerns that one might feel accompanies such a treatment hypotension, ventricular arrhythmias were similar at a level to placebo less than 1%. We had 28 serious adverse events. And very importantly, no torsades des pointes [ph].* Torsades des pointes is a lethal ventricular arrhythmias that arises with the other agent that is approved in the United States for pharmacologic conversion of atrial fibrillation (inaudible).

...

The Advisory Committee, it's Tuesday, and so this is my warm up, because I'm going to be speaking there. The consequences of that one will be, I think quite interesting for our company. We're very hopeful. And then the PDUFA date shortly thereafter, we do anticipate talking to the FDA. Obviously, we have to get a lot done in that very short period of time vis-a-vis labeling. In this first half of the year, we'll be looking to create a partnership and look for commercialization partner in the United States. We initially did those dialogues and I think the potential partners are waiting to see how the regulatory story will play out.

205. Defendants' statements were false and misleading because Defendants omitted and failed to disclose significant problems undermining the reliability of the SPECTRUM data, including that: (i) SPECTRUM's data was insufficient as SAE and AEs were underreported; (ii) SPECTRUM suffered from a selection bias; and (iii) the SPECTRUM study failed to consistently collect and record critical required information, such as heart rate and blood pressure readings, in violation of the SPECTRUM protocol; and (iv) the foregoing material deficiencies were so severe as to require Correvio to conduct additional studies to support a resubmitted NDA. Moreover, Defendant Corrigan's statement knowingly or extremely recklessly misrepresented Brinavess's prospects for FDA approval; while Defendants told investors they were "very hopeful" about the AdComm meeting and discussions with the FDA, Defendant Corrigan internally acknowledged in January 2019 that the Resubmitted NDA only had about a 50/50 chance of approval.

ADDITIONAL SCIENTER ALLEGATIONS

206. As alleged herein, Correvio and the Individual Defendants acted with scienter because Correvio and the Individual Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Correvio, their control over, and/or receipt and/or modification of Correvio's allegedly materially misleading misstatements and/or their associations with the

Company which made them privy to confidential proprietary information concerning Correvio, participated in the fraudulent scheme alleged herein.

207. The Individual Defendants knew or recklessly disregarded the false and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Individual Defendants.

208. The following additional facts give rise to strong inference that Correvio and the Individual Defendants acted with scienter.

209. Brinavess was the Company's primary and most important product and success of the Resubmitted NDA was undoubtedly crucial to the Company's viability and success. The Resubmitted NDA was Defendants' key focus during the Class Period. The fraud alleged herein involves Correvio's core operations. Knowledge of the fraud may therefore be imputed to the Individual Defendants.

210. With respect to the success of Brinavess and the Resubmitted NDA, Defendant Hunter acknowledged on multiple occasions, including on the March 13, 2019 earnings call, that the resubmitting the NDA was "the most important thing" the Company will do. Hunter stated, ***"Looking forward, the most important thing this company will do is file that NDA, have that NDA accepted and ideally move on to approval before the end of the year."***

211. As members of Correvio corporate management, Defendants had access to and reviewed reports and information about Correvio's safety data, including its SPECTRUM data, as well as the Company's NDA preparation.

212. According to CW1, the Company's executives, including Defendant Grant, received, among other updates, SPECTRUM annual safety reports including reports of any serious adverse events in accordance with good clinical practice guidelines. This included regular updates from Kiran Bhirangi, regarding the SPECTRUM PASS data, including safety data, which was regularly passed along from Quintiles. Indeed, the Company was receiving updates from Quintiles about the SPECTRUM study, fortnightly or weekly. This up-to-date information was passed along to Defendants. These updates were required under the 2016 Study Protocol.⁴⁷

213. During the course of the SPECTRUM trial, specifically, during the time when Correvio was finalizing the SPECTRUM trial, CW7, Defendant Grant's executive assistant from September 2017 to March 2018, reported that Grant met with Defendant Corrigan "once or twice a month, usually with her [regulatory] team in Vancouver – and a couple people joined from the U.S."

214. Defendants Hunter, Corrigan, Renz and Grant were intimately involved in planning and monitoring Correvio's operations, including managing the Resubmitted NDA. According to CW2, during the Company's April 2019, quarterly businesses review, a meeting attended by the leadership team (that included Defendant Renz, Defendant Corrigan, Defendant Grant, and Hugues Sachot, chief commercial officer) and country managers, Defendants discussed the Brinavess resubmission. CW2 recalled that "it was very clear that they [Defendants] were taking it [the resubmission] very seriously at that time."

215. According to the Company's 2018 40-F, Defendant Hunter served as a member of the Special Committee in charge of communications with the FDA regarding the Resubmitted

⁴⁷ See, e.g., 2016 Study Protocol at 11, 19, 33-35.

NDA. On the Company's March 13, 2019 earnings call, Defendant Hunter touted the Special Committee's work with the FDA including Defendant Corrigan's role in shepherding along the NDA package, "in fact, Mark [Defendant Corrigan] and Bob Meyer have been instrumental in the interaction with the FDA. We formed a special committee of the board, and those 2 have taken over a large part of the strategy and correspondence and interaction with the agency. And I think it's no small coincidence that we made such great progress last year on the Brinavess U.S. file as a result of that."

216. Defendants, especially Defendants Corrigan and Grant, worked closely on the Resubmitted NDA. CW4 recalled that executive leadership was "quite involved" in the application process. CW4 indicated that Defendant Grant "was running the process." In addition, CW4 reported, "I know Mark Corrigan was quite involved and was moving into CEO because this was his thing – regulatory filings. It was something he'd done a lot in his Pfizer days." CW6 also echoed CW4's recollection, noting that Defendant Grant was the one who pushed for the resubmission and centralized all the information. CW6 stated that Defendant Corrigan was really involved in the process of resubmission, from the beginning. CW6 was informed that Defendant Corrigan was present at all meetings regarding the Resubmitted NDA. CW2 provides a similar account, stating that CEO Mark Corrigan "would have been leading, and Sheila Grant would have been the medical affairs lead."

217. On Defendants' November 6, 2018 earnings call, Defendant Hunter acknowledged Defendant Grant's significant role in pushing the for Brinavess approval including managing the SPECTRUM trial. Defendant Hunter stated, "[a]nd in August of 2017, I respectfully asked people to stop asking me about Brinavess in the U.S. So we had to build a business that was completely independent of the U.S. opportunity. *Credit to Sheila, credit to the*

folks in Europe and the folks in SPECTRUM, they plugged away and they came up with a great study, and great data is the best way to open up opportunities, and that has done that for us.”

218. Further, Correvio and the Individual Defendants would have known about problems with the underreported SAEs and AEs, and the missing heart rate and blood pressure data from the SPECTRUM study. Correvio and its CRO had quality assurance measures in place for reviewing SPECTRUM data under the 2016 Study Protocol.⁴⁸ Correvio was also updated by the external safety review committee (“SRC”).⁴⁹ The quality control teams should have flagged problematic or missing data for Defendants, including missing heart rate and blood pressure readings taken (or not taken) during patients’ Brinavess infusions. This data is *essential* when monitoring a cardiac drug and was *required* under the 2016 Study Protocol.⁵⁰ Moreover, Defendant Grant is specifically listed as one of Correvio’s contacts to whom the CRO was to report issues.⁵¹ Defendants ignored red flags with the SPECTRUM data that would have been known to them in September 2018 when compiling SPECTRUM’s complete study report.

219. The 2016 Study Protocol’s requirements are corroborated by CW8, who was the lead investigator (physician) for the SPECTRUM trial conducted in Sweden at the Skane University Hospital in Malmo. CW8 reported to Jurgen Polifka at Cardiome in Germany, who was a director of marketing and market access from April 2013 to May 2018, and Correvio’s global marketing director since May 2018. CW8 recalled that the SPECTRUM study protocol

⁴⁸ 2016 Study Protocol, at 44.

⁴⁹ *Id.* at 45.

⁵⁰ *Id.* at 15.

⁵¹ *Id.* at 4.

required the patient's heart rate be monitored during the Brinavess infusion, and for a period afterwards. CW8 stated that under the protocol, the patient's blood pressure was monitored very fifteen (15) minutes during the Brinavess infusion.

220. The fact that some of the SPECTRUM clinical sites did not collect this required heart rate and blood pressure information would have been a major red flag that would have been brought to Defendants' immediate attention.

221. Further, given that Correvio was a very small Company, Individual Defendants had information and knowledge about all areas of the Company's business.

222. CW1 recalled that Correvio was a "small company," and noted that there were only a few team members working on the Brinavess trial. CW1 also explained that the SPECTRUM study "was really expensive for a tiny company. It was really important." CW4 corroborates this account, as CW4 recalled that that Correvio "was a small company, so everybody sort of knew everybody." CW2 noted that because Correvio was a small company, everyone in the Company understood the importance of the Resubmitted NDA. Specifically, CW2 stated, "we're not talking about Johnson & Johnson. We're talking about Correvio. We were all aware that the FDA piece was an important project throughout the Company." During the Class Period Correvio had approximately 135 employees.

223. The Individual Defendants were also well aware of the FDA regulatory practice, including the industry NDA requirements, by virtue of their extensive industry experience (*see* ¶¶ 38-41 *supra*). Defendant Corrigan was specifically selected for CEO in the Company's succession plan based on his experience dealing with FDA regulatory matters. Defendant Corrigan drew on this experience when he told the Company's global sales team that Brinavess's Resubmitted NDA only had ***about a 50-50 chance of getting approved***. Defendants understood

that FDA approval of the Resubmitted NDA was in no way guaranteed based on the SPECTRUM data gathered for Brinavess – especially given the study’s flaws. Further, like CW2, Defendants would have understood that the SPECTRUM registry contained bias, and that posed a significant concern as to the reliability of SPECTRUM’s safety data.

224. According to CW3, CW4 and CW5, Correvio also stopped selling Brinavess in Spain shortly after resubmitting the NDA, and had been regulating Brinavess sales in the UK during the Class Period. The Resubmitted NDA included spontaneous analysis of postmarketing adverse event cases reported from areas where Brinavess was approved for marketing. This would have included any potential adverse event cases from the UK and Spain. CW3 believed the Company suspected a problem with Brinavess’s approval when it made the decision to stop promoting Brinavess in Spain.

225. Each of the Individual Defendants was a high-ranking management-level employee. The scienter of each of the Individual Defendants and of all other management-level employees of Correvio, including each high-ranking officer or director, is imputable to the Company. The knowledge of each of these individuals should therefore be imputed to Correvio for the purposes of assessing corporate scienter.

226. Even aside from the scienter of the Individual Defendants, the facts alleged herein raise a strong inference of corporate scienter as to Correvio as an entity. Corporate scienter may be alleged independent of individual defendants where a statement is made or approved by a corporate official sufficiently knowledgeable about the company to know the statement was false or misleading. Here, the statements alleged were made to the investing public regarding the Company’s operations—an important topic that would necessarily require approval by

appropriate corporate officers who, as alleged, had very different information in their hands at the time from what was disclosed to investors.

CLASS ACTION ALLEGATIONS

227. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Correvio securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

228. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Correvio securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Correvio or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

229. Plaintiffs’ claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants’ wrongful conduct in violation of federal law that is complained of herein.

230. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

231. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Correvio;
- whether the Individual Defendants caused Correvio to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Correvio securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

232. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD ON THE MARKET)

233. The market for Correvio's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Correvio's securities traded at artificially inflated prices during the Class Period. On March 12, 2019, the Company's share price closed at a Class Period high of \$4.20 per share. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Correvio's securities and market information relating to Correvio, and have been damaged thereby.

234. During the Class Period, the artificial inflation of Correvio's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Correvio's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Correvio and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

235. At all relevant times, the market for Correvio's securities was an efficient market for the following reasons, among others:

a. Correvio shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. As a regulated issuer, Correvio filed periodic public reports with the SEC and/or the NASDAQ;

c. Correvio regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

d. Correvio was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace; and/or

e. The average daily trading volume for Correvio securities during the Class Period was approximately 267,501 shares with 41,305,709 shares outstanding as of June 30, 2019, and a market capitalization reaching over \$164 million during the Class Period.

236. As a result of the foregoing, the market for Correvio's securities promptly digested current information regarding Correvio from all publicly available sources and reflected such information in Correvio's share price. Under these circumstances, all purchasers of Correvio's securities during the Class Period suffered similar injury through their purchase of Correvio's securities at artificially inflated prices and a presumption of reliance applies.

237. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material

misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

LOSS CAUSATION

238. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class. During the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements and omissions about Correvo's prospects to obtain approval of the Resubmitted NDA. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements and omissions during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

CLAIMS FOR RELIEF

FIRST CLAIM

**Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated
Thereunder
Against All Defendants**

239. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

240. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

241. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Correvio securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Correvio securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

242. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Correvio securities. Such reports, filings, releases and statements were

materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Correvio's finances and business prospects.

243. By virtue of their positions at Correvio, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

244. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Correvio, the Individual Defendants had knowledge of the details of Correvio's internal affairs.

245. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Correvio. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Correvio's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Correvio securities was artificially inflated throughout the Class Period. In

ignorance of the adverse facts concerning Correvio's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Correvio securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

246. During the Class Period, Correvio securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Correvio securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Correvio securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Correvio securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

247. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

248. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure

that the Company had been disseminating misrepresented statements regarding its prospects to the investing public.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

249. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

250. During the Class Period, the Individual Defendants participated in the operation and management of Correvio, and conducted and participated, directly and indirectly, in the conduct of Correvio's business affairs. Because of their senior positions, they knew the adverse non-public information about Correvio's misstatements regarding its business and operations.

251. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Correvio's operations, and to correct promptly any public statements issued by Correvio which had become materially false or misleading.

252. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Correvio disseminated in the marketplace during the Class Period concerning Correvio's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Correvio to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Correvio within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Correvio securities.

253. Each of the Individual Defendants, therefore, acted as a controlling person of Correvio. By reason of their senior management positions and/or being directors of Correvio, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Correvio to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Correvio and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

254. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Correvio.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

DATED: Los Angeles, California
May 1, 2020

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PROOF OF SERVICE

I, the undersigned say:

I am not a party to the above case and am over eighteen years old.

On May 1, 2020, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the Southern District of New York, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on May 1, 2020.

s/ Kara M. Wolke
Kara M. Wolke